State of California Department of Consumer Affairs

Memorandum

To: **Board Members** **Date: July 15, 2006**

From: **Organizational Development Committee**

Subject: **Committee Actions and Update of the Meeting of July 11, 2006**

The Organizational Development Committee met in a nonpublic, teleconferenced meeting on July 11, 2006. A meeting summary is provided at the back of this tab section as Attachment 1.

For Approval:

ITEM 1. Approval of the Committee's Strategic Plan:

The committee's strategic plan is provided in Attachment A, and is being submitted for board approval.

ITEM 2. Approval of the Board's Strategic Plan 2006-2011:

The board's strategic plan for 2006-11 needs to be approved.

In Attachment B is the front matter portion of the strategic plan (without the addition of each of the committee's strategic goals, objectives and activities, which have been individually reviewed and approved by the board during this meeting). Changes made to the plan made by the board during the April Board meeting have been incorporated into this manuscript.

Approval of this material, when combined with each of the committee components previously approved during this board meeting, will comprise the entire plan.

ITEM 3: Recognition of Pharmacists Who Have Been Licensed 50 Years:

At the July 2005 Board Meeting, the board initiated a program to identify and publicly commend those pharmacists with 50 years of licensure as pharmacists.

The pharmacists so honored receive a letter from the board's president and a commendation certificate. Each is invited to a future board meeting to be publicly recognized. Additionally, his or her time is published in *The Script.*

Since July 2005, the board has acknowledged 573 pharmacists:

July 2005:	450 pharmacists
Oct. 2005:	50 pharmacists
Jan. 2006:	8 pharmacists
Apr. 2006:	8 pharmacists
July 2006:	57 pharmacists

Recognition of the pharmacists with 50 years of service who attend this board meeting will occur at this point in the meeting.

ITEM 4: Executive Officer Recruitment and Selection Process

During this part of the meeting, the Department of Consumer Affairs Personnel Office will present information on a recruitment process for selecting an executive officer.

Materials developed by the Personnel Office for this process are provided in Attachment C.

Following this presentation, the board will discuss how it will recruit and select the next executive officer.

For Information:

ITEM 5. NABP National Meeting in San Francisco in April 2006, and Districts VII and VIII Meeting in Anaheim in October 2006:

This year, two of the National Association of Boards of Pharmacy meetings have been scheduled in California:

- April 2006: The NABP annual meeting took place in San Francisco. The NABP recently thanked the board for its assistance as the host state in providing assistance in the hospitality suite.
- October 2006: The NABP Districts VII and VIII meeting will be in Anaheim.

A draft agenda has been developed for the District VII and VIII meeting by former Executive Officer Harris, Dr. Sam Shimomura of Western University, and Virginia Herold. This draft agenda is provided in Attachment D

All board members are invited to attend this regional meeting.

ITEM 6: Personnel Update

1. Executive Officer Resignation

Executive Officer Harris was appointed as Deputy Director, Bureau Relations in the Department of Consumer Affairs by Governor Schwarzenegger on July 1, 2006. With this appointment, Patricia Harris resigned her position as executive officer.

Executive Officer Harris has been with the board for 25 years – she came as the enforcement coordinator, became assistant executive officer and since 1990, has been the executive officer. At some point during this meeting, which Ms. Harris is expected to attend briefly, she will be acknowledged by the board. A reception in her honor will be scheduled for the October Board Meeting.

On July 1, Vice President Ken Schell, acting in the absence of President Bill Powers, appointed Virginia Herold as acting executive officer until the next meeting of the board.

At the July Board Meeting, the board will appoint an interim executive officer, until such time as a permanent executive officer can be appointed.

2. Inspector Vacancies and Recruitment Efforts

The board has lost two inspectors since the April Board meeting:

- Inspector Jeff Smith, who has been with the board over five years, who was assigned to the drug diversion team and was the board's computer guru, transferred to the Department of Health Services at the beginning of July.
- Inspector Robert Grimm, who has been with the board for about 10 years on the compliance team transferred to a dispending pharmacist position at a correctional facility in Orange County.

Both inspectors transferred to positions where they will make at least $24,000 more annually than at the board. This salary inequity has been a long-standing problem, and the board's staff has recently begun activities to secure a salary adjustment for its pharmacists.

When Inspector Smith resigned at the end of June to transfer to the Department of Health Services, he immediately received an annual salary $24,000 more than at the board due to a "recruitment and retention differential" paid by some state employers of pharmacists, like the Department of Health Services. This is necessary because private sector pharmacists make salaries of $110,000 annually.

Board staff hope to present a successful case for a similar augment for board inspectors. If approved there will be an annual increase to each inspector and supervising inspector of $24,000 annually, raising inspector salaries to $99,660 and supervising inspector salaries to $103,460. The annual increase from these salaries to the board will be $552,000.

The board has four inspector vacancies:

- A new, restored position effective 7/1/06
- Jeff Smith's position
- Bob Grimm's position
- Nahal Bahrampour's position (vacant since 3/06)

The board is working with the department's Personnel Office to schedule a new civil service examination from which pharmacists can be hired to work for the board. This process will take at least four more months, and we hope to fill these positions in the fall. This is a priority for the board's senior staff.

Dennis Ming, a supervising inspector for the last three years, resigned on June 30, 2006. Dr. Ming was a supervisor of the compliance team. Dr. Ming will remain on the board's staff as a retired annuitant.

The board is also working with the department on a new civil service examination for supervising inspector. Again, this process will likely take four more months and this position should be filled in the fall: this is also a priority for the board's senior staff.

3. Other Staff Changes:

The board has made several personnel changes since the April meeting:

- Anne Sodergren has become the board's Legislative Manager, replacing Jan Perez whose training and development assignment ended in April.
- Christine Sanchez has joined the board as the new Licensing Unit Manager, replacing Ms. Sodergren. Ms. Sanchez formerly worked for the Womens, Infant and Childrens program in the Department of Health Services.
- Julie Baker has become the board's new receptionist, a position that was restored by the state budget on July 1. Ms. Baker formerly worked for the California Highway Patrol. And in early July, Ms. Baker was appointed to a technician position in the board's executive office where she will eventually replace Candy Place, who will retire in November. Ms. Baker will attend this meeting.
- Nicole Mullnix has joined the board as a part-time receptionist, she formerly worked as a student assistant at the Department of General Services.

The board is recruiting for the following positions:

- A part-time manager/specialist position to serve as coordinator of the Pharmacists Recovery Program.
- An associate analyst to develop consumer and licensee educational materials.
- A budget analyst and business position (duties currently performed in part

by Ms. Place).
- An enforcement analyst.
- A receptionist to replace Julie Baker
- A seasonal clerk to perform filing and mailing duties.

4. Board Members:

Ken Schell, PharmD., was appointed July 1 to a second term by Governor Schwarzenegger.

Also, Susan Ravnan, PharmD., was appointed July 1 to the union pharmacist member position on the board.

Board Member Marion Balay resigned from the board in May.

The board currently has four public board member positions and two professional member positions vacant. All are governor appointments.

5. Specialized Training:

All board staff completed a 12-hour, two-day team building training called "colors." The training focuses on individuals' working styles, personality traits and working together.

ITEM 7: Budget Update and Report

I. Budget Report for 2005/06

The prior fiscal year ended June 30, 2006. Final figures of revenue and expenditures will not be available until mid-August, so the figures provided below are estimates. A final budget report for the year will be provided to the board at the October meeting.

Revenue Projected: $9,120,296

This fiscal year the board received repayment of $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund. This repayment is classified as revenue for the year. (Three million dollars is still owed to the board from the 2001 loan.)

The board's revenue for the year is projected to be comprised of:

Licensing Fees (estimated):	$5,360,000
Interest	$90,000
General Fund Loan repayment	$3,227,000
Cite & Fine (actual as of 6/30/06)	$273,969
Cost Recovery (actual as of 6/30/06)	169,327
	$9,120,296

The projected revenue from fees is conservative and traditionally is about 10 percent less than actual revenue will be.

Expenditures Projected: $7,954,121

The board's maximum expenditure authority for the year was $7.9 million. The board did spend all of this allocation.

II. Governor's Proposed Budget for 2006/07

The budget for the fiscal year that started July 1, 2006, is in place.

Revenue Projected: $8,356,000

Revenue for the year is projected to be comprised of $5,316,000 in fees and $40,000 in interest on money in the board's contingency fund.

The board is currently projected to receive this year the final repayment of $3 million from the 2001 loan of $6 million from the board's fund to the state's General Fund during a period of California's budget crisis.

Expenditures Projected: $8,446,000

Expenditures for the new fiscal year are $240,000 more than those projected for the last fiscal year. This increase includes:

- -- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000's. ($208,000)
- -- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)

The board will receive restoration of one inspector position, one receptionist position and one half-time public outreach position. The receptionist position has been filled, and the board is recruiting for the public outreach position, which will be filled on a full-time basis. The board is working with the department's Personnel Officer to provide a civil service examination so we can fill the inspector position.

III. Board Fund Condition

The board's fund condition displays whether its revenue collected is sufficient to sustain expenditures. Over the last few years, the board's annual expenditures typically have exceeded its annual collected revenue. Normally this would be a huge problem that would trigger budget cutbacks or fee increases, but the board has had a surplus of money in its fund (which can be thought of as the board's savings account). The board has been trying to spend down this surplus for several years, eliminating a surplus condition caused by the 1999 repayment of a

loan to the state's General Fund (during another budget crisis in the early 1990s).

The board must watch its fund condition carefully, however, because if it gets low or into a deficit, the board will run out of money for annual operations (since expenditures exceed revenue collected). The Business and Professions Code provides that the board should maintain a reserve of 12 months of annual expenditures as a prudent reserve. However, state budget officials do not agree that this much money needs to be kept as the board's reserve. They prefer a reserve of 3-6 months.

The board ended the last fiscal year (on June 30, 2006) with a projected reserve of $4,834,000. This is 7.1 months of expenditures.

The board's fund condition projections over the next few years (as estimated in early May 2006) are:

- 2006-07: A reserve of 7.2 months is projected.
- 2007-08: A reserve of 2.8 months is projected.
- 2008-09: A deficit in the reserve of is projected of –1.7 months

A copy of the board's fund condition is provided in Attachment E.

A fee increase may be needed to take effect July 1, 2008 to prevent a deficit during 2008-09. Board staff will continue to watch these figures closely.

IV. Board Member Expenditures and Reimbursements

The travel expenses and compensation of board members claimed during the last fiscal year is provided as Attachment F.

Board members are paid for their attendance at board meetings. If they are interested in pursuing payment for other duties, board members can receive $100 for every 8 hours they spend reading board materials, voting on mail ballots or otherwise performing approved duties. (Travel time is not reimbursed.) Please use the board member attendance report to submit these hours.

ITEM 8. Board Member Procedure Manual

For a number of years, the board has provided to its board members a specially developed *Board Member Procedure Manual* to aid them as a reference in performing board duties. This manual is in addition to the new board member orientation training provided to the board members by the Department of Consumer Affairs.

The committee has approved some changes to the manual to reflect policies it has developed over the last few years. The manual itself has also been redesigned to improve its appearance.

However, this item was not listed on the agenda for action at this meeting, and will be brought to the October Board Meeting for review and approval.

ITEM 9: Proposed Meeting Dates for 2007

The committee has agreed to a staff proposal to move the July 2007 board meeting, which has traditionally been in San Diego, to another location (to switch the location with the January board meeting which is usually scheduled for LA/Orange County).

The reason for this move is that for the last two years, trying to arrange a board meeting in July in San Diego has been difficult and expensive. As a resort community, the areas downtown (that are near the airport) are very expensive during the summer. For example, this year, an overnight room at a downtown hotel is well over $250 and in some hotels exceeds $300. Had the 2006 board meeting been in San Diego as initially scheduled, the cost of the meeting room with the necessary sound system would have exceeded $7,300, and each overnight room would have been $175.

The proposed board meeting dates and locations are:

2006

- October 25 and 26 – San Francisco/Bay Area *(CSHP's Seminar is in Sacramento on Oct 12-15)*

2007

- January 31 and February 1 -- San Diego *(CPhA's Outlook is February 15-18 in Palm Springs)*
- April 18, 19 – Sacramento *(NABP's Annual Meeting is in Portland Oregon in May)*
- July 25, 26 – Los Angeles/Orange County
- October 24 and 25 -- San Francisco/Bay Area *(CSHP's Seminar is October 18-21 in Palm Springs*

ITEM 9. Update on I-Licensing Project – Online License Application and Renewal:

Approximately seven DCA agencies have the ability to provide online license renewal due to participation in a project started under the Davis Administration. However, the state's budget crisis in the early 2000s prevented the Board of Pharmacy from joining this project, although the board has been striving to be added for years.

The Department of Consumer Affairs is now moving ahead with a proposal so other interested agencies can offer online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future.

A budget change proposal will need to be written and approved for the board to participate in this project in the future as well. The DCA will be developing this budget change proposal for all participating agencies.

No costs are yet available for this conversion, and it will be at least one year from implementation at the board.

Attachment A

Organizational Development Committee's Strategic Plan Components

Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.**
Outcome:	**An effective organization**

Objective 5.1:	**Obtain 100 percent approval for identified program needs by June 30, 2011.**
Measure:	**Percentage approved for identified program needs**
Tasks:	1. Review workload and resources to streamline operations, target backlogs and maximize services. 2. Develop budget change proposals to secure funding for needed resources. 3. Perform strategic management of the board through all committees and board activities. 4. Manage the board's financial resources to ensure fiscal viability and program integrity.

Objective 5.2:	**Maintain 100 percent staffing of all board positions.**
Measure:	**Percentage staffing of board positions**
Tasks:	1. Continue active recruitment of pharmacists for inspector positions. 2. Vigorously recruit for any vacant positions. 3. Perform annual performance and training assessments of all staff.

Objective 5.3:	**Implement 10 strategic initiatives to automate board processes by June 30, 2011.**
Measure:	**Number of strategic initiatives implemented to automate board processes**
Tasks:	1. Implement automated applicant tracking (ATS). 2. Implement online license renewal and application submission features (I-Licensing). 3. Integrate telephonic features to improve board services without adding staff resources. 4. Use the department's newly created "ad hoc" system to generate data for reports.

Objective 5.4:	**Provide for communication venues to communicate within the board by June 30, 2011.**
Measure:	**Number of communication venues to communicate within the board**
Tasks:	1. Continue the Communication Team to improve communication among staff and host quarterly staff meetings. 2. Continue Enforcement Team meetings with board members and enforcement staff. 3. Convene annual inspector meetings to ensure standardized investigation and inspection processes, law and practice updates and earn continuing education credit.

Objective 5.5:	**Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed.**
Measure:	**Number of outreach programs conducted in one year**
Tasks:	1. Convene the Subcommittee on Medicare Part D Implementation 2. Convene the Workgroup to implement the e-Pedigree 3. Host the National Association of Boards of Pharmacy District 7 and 8 Meeting in California 4. Attend outreach programs.

Objective 5.6: **Measure:**	**Respond to all public record requests within 10 days.** **Percentage response to public record requests within 10 days**
Tasks:	1. Respond to public records requests within 10 days (e.g., license verifications, investigative information, licensing information). 2. Respond to subpoenas within the timeline specified. 3. Respond to specific requests for data reports

STRATEGIC ISSUES TO BE ADDRESSED
Organizational Development Committee

1. Cost of medical/pharmaceutical care

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription drug costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacies. However, the cost of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this marketplace, the former endanger public health and confidence in the prescription drugs patients take.

Objectives:

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

2. Aging population

There are increasingly more senior citizens, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand.

Many senior citizens, who previously may not have had prescription drug insurance coverage, will benefit from the new prescription drug benefit of Medicare that started in January 2006. However, this new benefit has been implemented with significant problems for some seniors, and as a complicated new program, will require public education and perhaps statutory modification.

Objectives:

5.2 Maintain 100 percent staffing of all board positions

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

5. Laws governing pharmacists

New laws enhancing pharmacists' roles as health care providers are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by

pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

6. Integrity of the drug delivery system

Implementation of the e-pedigree for prescription drugs will reduce the growing incidence of counterfeit medications in California's pharmacies. Additionally the federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to emergency preparedness, disaster response and pandemics. Changes in the prescription drug benefits provided to Medicare beneficiaries will continue to command attention.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.3 Implement 10 strategic initiatives to automate board processes by June 30, 2011

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

7. Technology Adaptation

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and 'channeling' to locations other than a traditional pharmacy may become the business model. Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues. New medication, perhaps engineered for specific patients, will become available at high costs and require special patient monitoring systems.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.3 Implement 10 strategic initiatives to automate board processes by June 30, 2011

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely impaired with continued resource constraints by both the federal and state agencies with jurisdiction.

Objectives:

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.3 Implement 10 strategic initiatives to automate board processes by June 30, 2011

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

10. Qualified staff

The state's fiscal crisis has affected the board's ability to investigate customer complaints or hire staff. The board lost 20 percent of its staff during the prior four years due to the state's hiring freezes. Loss of these staff has altered the provision of services by the board. The salary disparity between the private and public sectors in compensation for pharmacists will make it difficult to recruit and retain pharmacist inspectors. Moreover, for all staff, if wages remain essentially frozen, the retention of current employees could be impacted.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

5.2 Maintain 100 percent staffing of all board positions

5.3 Implement 10 strategic initiatives to automate board processes by June 30, 2011

5.4 Provide for communication venues to communicate within the board by June 30, 2011

5.6 Respond to all public record requests within 10 days

11. Pharmacy/health care in the 21st century

The state's health care practitioners (pharmacists, physicians, nurses) are being influenced by a variety of internal and external factors that affect and will continue to effect health care provided to patients. Improved patient care will result from improved integration among these professions. Also, a renewed emphasis on patient consultation will benefit patient knowledge about their drug therapy and thus improve their care.

Objectives:

5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

12. Information Management

Creation, maintenance and transfer of electronic patient records and prescription orders will be the norm in the future. Patient records need to remain confidential and secured from authorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed. It is likely that all controlled drugs dispensed in California will be tracked electronically by the CURES system.

Objectives:

5.1 Obtain 100 percent approval for identified program needs by June 30, 2011

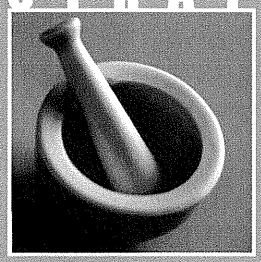
5.2 Maintain 100 percent staffing of all board positions

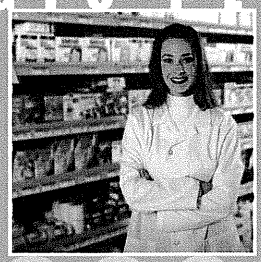
5.5 Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed

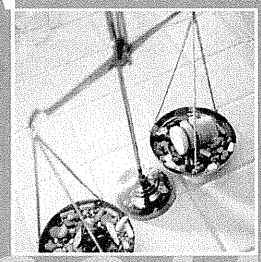
Attachment B

Board of Pharmacy's 2006-011 Strategic Plan

STRATEGIC PLAN







2006-2011

CALIFORNIA STATE BOARD OF PHARMACY

Healthy Californians Through Quality Pharmacist's Care

California State Board of Pharmacy

STRATEGIC PLAN

2006-2011

Members:
William Powers, Public Member, President
Kenneth Schell, Pharm.D., Pharmacist Member, Vice President
Ruth Conroy, Pharm.D., Pharmacist Member, Treasurer

Clarence Hiura, Pharm.D., Pharmacist Member
Stanley Goldenberg, Pharmacist Member
Susan Ravnan, Pharm.D., Pharmacist Member
Andrea Zinder, Public Member

Virginia Herold, Acting Executive Officer

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July 2006

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PRESIDENT'S MESSAGE

The strategic planning process of the California State Board of Pharmacy is an annual effort of the board members, staff and the public to anticipate and plan for events and issues for the coming year. Although the board considers its current strategic plan when going through the planning exercise, the board also attempts to predict upcoming changes in pharmacy practice, consumer needs and demands and health care trends. After a lengthy discussion of potential and existing issues, the participants go through a process to categorize, consolidate and finally prioritize the issues and then set the goals for the coming year. The resulting strategic plan keeps the board focused on established goals while allowing the flexibility of handling new questions and challenges as they arise.

Each board committee considers its individual strategic plan goals at every meeting and the progress on the goals are reviewed at each of the quarterly full board meetings. The careful planning and continuous monitoring of the strategic plan assures that the board achieves its stated objectives and performs with optimal efficiency.

The board publishes advance notice for each strategic planning meeting and encourages participation and contribution by all interested citizens of California who attend. Involvement of the board, its staff and the public results in a strategic plan that truly represents the public interest and serves the consumers of this state.

CALIFORNIA STATE BOARD OF PHARMACY

Vision Statement

Healthy Californians through quality pharmacist's care.

Mission Statement

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.

SHARED VALUES/CORE PRINCIPLES

The Board of Pharmacy will exhibit:

- Vision
- Integrity
- Flexibility
- Commitment
- Loyalty to its mission
- Relevance to important issues
- Compassion, and
- Open-mindedness

These values will be exhibited when considering all matters before the board affecting the consumers of California and the profession of pharmacy.

About the California State Board of Pharmacy

The California State Board of Pharmacy (board) was established in 1891 to protect consumers by licensing and regulating those responsible for dispensing medications to the public. Today the board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacists), the practice site (the pharmacies), and the product (drugs and devices). Additionally the board regulates drug wholesalers and other practitioners and specialized facilities. With an annual budget of nearly $8 million and a staff of just over 50, the board licenses over 90,000 individuals and firms, and enforces 12 complex and varied regulatory programs.

The board has five policy development committees to fulfill its charge. The five committees are: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Each of these committees corresponds to a mission-related goal.

The board supports an active Web site, www.pharmacy.ca.gov, that provides consumer education material, application material for licensing and information for ensuring compliance with California Pharmacy Law . The Web site also provides times and information on board meetings as well as other critical forums vital to pharmacy services were public comments and input are sought and encouraged.

SCANNING ASSESSMENT AND METHODOLOGY

In assessing the critical data that will influence the board's ability to fulfill its vision and mission, the strategic planning team completed several scanning activities in 2006. Board members, all staff and stakeholders participated in completing a survey questionnaire that was submitted to the strategic planning team for synthesis and analysis. This included review of the board's mission, vision, goals and strategic issues. Additionally a "SWOT" analysis (an acronym for strengths, weaknesses, opportunities and threats) was conducted during the survey as part of the scanning assessment.

In developing its strategic plan, the board relied upon the full participation of its entire staff, its board members and its interested stakeholders. The participation of each group has provided important information necessary for a dynamic strategic plan, capable of guiding the board in fulfilling its mission for several years.

After each group performed the SWOT analyses described above, the board refined the strategic issues to be addressed during the April 2006 Meeting, and the results are summarized in this plan under "**Strategic Issues to be Addressed.**"

Additional refinement of board objectives and activities was conducted during late spring 2006 by each of the board's strategic committees, and the final strategic plan for 2006-11 was approved at the July 2006 Board Meeting.

STRATEGIC ISSUES TO BE ADDRESSED

1. Cost of medical/pharmaceutical care

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription drug costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacies. However, the cost of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this marketplace, the former endanger public health and confidence in the prescription drugs patients take.

2. Aging population

There are increasingly more senior citizens, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand. Specialized training of pharmacists may be necessary to better serve the needs of aging patients.

Many senior citizens, who previously may not have had prescription drug insurance coverage, will benefit from the new prescription drug benefit of Medicare that started in January 2006. However, this new benefit has been implemented with significant problems for some seniors, and as a complicated new program, will require public education and perhaps statutory modification.

3. Pharmacists' ability to provide care

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

4. Changing demographics of California patients

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

5. Laws governing pharmacists

New laws enhancing pharmacists' roles as health care providers are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus nonselling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

6. Integrity of the drug delivery system

Implementation of the e-pedigree for prescription drugs will reduce the growing incidence of counterfeit, damaged, adulterated or misbranded medications in California's pharmacies. Additionally the federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to emergency preparedness, disaster response and pandemics. Changes in the prescription drug benefits provided to Medicare beneficiaries will continue to command attention.

7. Technology Adaptation

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and "channeling" to locations other than a traditional pharmacy may become the business model. Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues. New medication, perhaps engineered for specific patients, will become available at high costs and require special patient monitoring systems.

8. Internet issues

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely impaired with continued resource constraints by both the federal and state agencies with jurisdiction.

9. Disaster planning and response

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters, pandemics and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized. Specialized drug distribution channels will need to be authorized to permit emergency response.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

10. Qualified staff and Board Members

The state's fiscal crisis has affected the board's ability to investigate customer complaints or hire staff. The board lost 20 percent of its staff positions during the prior five years due to the state's hiring freezes. Loss of these staff has altered the provision of services by the board. The salary disparity between the private and public sectors in compensation for pharmacists will make it difficult to recruit and retain pharmacist inspectors. Moreover, for all staff, if wages remain essentially frozen, the retention of current employees could be impacted.

The diversity and involvement of all board members in policy development is important for public health and protection. At least a quorum of board members is needed to ensure the board can make decisions and act timely.

11. Pharmacy/health care in the 21st century

The state's health care practitioners (pharmacists, physicians, nurses) are being influenced by a variety of internal and external factors that affect and will continue to effect health care provided to patients. Improved patient care will result from improved integration among these professions. Also, a renewed emphasis on patient consultation will benefit patient knowledge about their drug therapy and thus improve their care.

12. Information Management

Creation, maintenance and transfer of electronic patient records and prescription orders will be the norm in the future. Patient records need to remain confidential and secured from unauthorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed. It is likely that all controlled drugs dispensed in California will be tracked electronically by the CURES system.

INTERNAL/EXTERNAL ASSESSMENT

The critical data stemming from the SWOT analysis is reflected below. The information represents a deliberative process of multiple iterations conducted with the board members, staff and stakeholders.

Strengths	Weaknesses
1. Staff/Inspectors: Staff's teamwork, dedication, diversity, and knowledge. Pharmacist inspectors provide necessary, specialized knowledge. 2. Leadership: Support and communication provided by management, diversity and experience of board members.	1. Resources: Budget constraints and insufficient resources to meet mandated duties at desired levels 2. Staffing Shortages: Insufficient staff to perform, manage, and review consumer protection activities of licensing, enforcement, and education programs.

Opportunities	Threats
1. Pharmacist's Role: Pharmacy profession has large potential role in healthcare delivery. Pharmacists have opportunities in roles associated with patient care and not exclusively dispensing. 2. Technology/Automation: Promoting legislation and regulations to foster the use of technological advances by pharmacies, attainment of operational efficiencies, decreased administrative burdens, and enhanced patient care services. 3. Consumer Safety/Privacy: Promoting a nonpunitive learning environment approach to improving pharmacy patient safety. Continuing emphasis on patient safety by involving	1. Board of Pharmacy staffing is insufficient to perform mandated duties at desired levels. 2. Board funding: Lack of funding for new programs; lack of fiscal control of board over much of its budget; budget constraints and deficits; hiring freeze. 3. Cost of pharmaceuticals: Impacts of the increasing costs of pharmaceuticals cannot be managed or controlled by the consumer or the board.

the pharmacist in patient care. 4. Public education: Increasingly informed consumers means the profession must be able to deliver public education on drug use safety and healthcare issues.	4. Pharmacy personnel shortage: Lack of licensees impedes the ability of patients to receive quality pharmacists care.

SUMMARY OF GOALS

Goal One

Exercise oversight on all pharmacy activities.

Goal Two

Ensure the qualifications of licensees.

Goal Three

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Goal Four

Provide relevant information to consumers and licensees.

Goal Five

Achieve the board's mission and goals.

Goals, Outcomes, Objectives, and Measures

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Please substitute the Goals, Objectives and Tasks of the Enforcement Committee as approved earlier in this board meeting.

Licensing Committee

Goal 2: Ensure the qualifications of licensees.
Outcome: Qualified licensees

Please substitute the Goals, Objectives and Tasks of the Licensing Committee as approved earlier in this board meeting.

Legislation and Regulation Committee

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Please substitute the Goals, Objectives and Tasks of the Legislation and Regulation Committee as approved earlier in this board meeting.

Communication and Public Education Committee

Goal: 4:	**Provide relevant information to consumers and licensees.**
Outcome:	**Improved consumer awareness and licensee knowledge.**

Please substitute the Goals, Objectives and Tasks of the Communication and Public Education Committee as approved earlier in this board meeting.

Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.**
Outcome:	**An effective organization**

Please substitute the Goals, Objectives and Tasks of the Organizational Development Committee as approved earlier in this board meeting.

Goal Alignment Matrix – Strategic Issues

	Goal 1: Exercise oversight on all pharmacy activities	Goal 2: Ensure the qualifications of licensees.	Goal 3: Advocate legislation and promulgate regulations that advance the Vision and Mission of BOP.	Goal 4: Provide relevant information to consumers and licensees.	Goal 5: Achieve the Board's Mission and Goals.
Strategic Issues					
1. Cost of medical/pharma-ceutical care	X		X	X	X
2. Aging population	X	X		X	X
3. Pharmacists' ability to provide care	X	X	X	X	X
4. Changing demographics of CA patients	X	X		X	X
5. Laws governing pharmacists	X	X	X	X	
6. Integrity of the drug delivery system	X	X	X		
7. Technology adaptation	X		X	X	X
8. Internet Issues	X			X	X
9. Disaster planning and Response	X	X	X	X	X
10. Qualified staff	X	X			X
11. Pharmacy/ Healthcare Integration in the 21st century	X	X	X	X	X
12. Information Management	X	X	X	X	X

Attachment C

Executive Officer Recruitment Materials

State of California **Department of Consumer Affairs**

Memorandum **Date:** July 17, 2006

To: Board Members
Board of Pharmacy

From: Karen Cates, Staff Services Manager

Subject: Executive Officer Recruitment

With the recent appointment of Executive Officer Patricia Harris to Deputy Director, Bureau Relations of the Department of Consumer Affairs, the board will be determining at this meeting the process they wish to take to recruit a new Executive Officer.

Attached for your review is a sample timeline for Executive Officer recruitment and the board's job duty statement for this position. A representative of the Department of Consumer Affairs' Office of Human Resources will be giving a presentation on the various avenues the board can choose for the recruitment process, such as establishing a selection committee to assist in the recruitment effort.

After the presentation, the board, in open session, will determine the recruitment process they wish to pursue. If the board decides to appoint a selection committee to screen applications and perform initial interviews, only two board members can be appointed to this committee. When more than two members of the board meet, it is considered a public meeting and requires the appropriate written public notice.

Final interviews of candidates are conducted by the full board in closed session and the meeting must conform to the public notice requirements for Board meetings.

During the recruitment process, I will be acting as the board liaison with the Office of Human Resources.

Attachment A

SAMPLE TIMELINE
EXECUTIVE OFFICER RECRUITMENT
BOARD of _____

DUE DATE	TASK	OWNER	COMMENTS
START: Board meeting	Review EO duty statement; draft revisions, if necessary	Board/Human Resources	
Board meeting	Form Selection Committee	Board Members	2 Board members (may also include 1 DCA representative)
Board meeting + 1	Post job opportunity on DCA/SPB website	HR	
TBD (2 weeks)	Finalize External Advertisement	HR/Selection Committee	1. Send to state agencies, if requested 2. Determine: • Budget for advertisement • List of publications • Advertisement period 3. Obtain quotes from pubs
	Prepare Purchase Orders for ads	Board staff	
	Submit ad to identified publications	HR/Bd staff	
Concurrent w/advertisement	Develop screening criteria -desirable or minimum qualifications	Selection Committee (HR input)	Provides objective criteria - not mandatory, but extremely beneficial in speeding up the process
Concurrent w/advertisement **or** After FFD	Receive, review and screen apps to identify most qualified candidates	Selection Committee	
Concurrent w/advertisement	• Develop interview questions • Determine interview site	Selection Committee	HR input available
START + 2-4 weeks (min)	**Final Filing Date**	HR	Provide Committee with final app/resumes w/in 5 days
	Return rejected apps to HR	Selection Committee	
	Notify rejected applicants by mail	HR/Bd staff	Samples available in HR
FFD + 2 weeks (minimum)	Schedule interviews	HR/Bd staff	Notices mailed 7-10 days prior to interview date
	Conduct interviews; identify top candidate(s)	Selection Committee	• May choose to interview top candidates at Board Meeting
Interview date + 7	Written notification to candidate(s) not selected	HR/Bd staff	Samples available in HR
START + 2 months	Board meeting – Board may: • Conduct 2nd interview of several candidates to decide on top selection; or • Vote to accept recommendation of Selection Committee w/o further interviews	Board members	• Closed session • Special meeting may be necessary to meet timeframe for selection • Quorum required • Vote required for record
TBD	• Determine start date and salary for selected candidate • Notify HR in writing	• Board members • Board Chair	
Bd meeting +2 days	Written notification to candidate(s) not selected	HR/Bd staff	Samples available in HR
TBD	New Executive Officer starts		Oath of Office **required** prior to official start date. May be administered by Board member

Rev 6/2006

DUTY STATEMENT

Classification: Executive Officer, Board of Pharmacy	Division: Executive
Work Title: Executive Officer	Section:
Collective Bargaining Unit: Non-represented (E99)	Position #: 632-110-8916-001

Scope of Regulation

The Board of Pharmacy is a consumer protection agency charged with protecting the states' consumers with respect to prescription drugs and devices. The board regulates all aspects of pharmacy practice in California and provides protection of the public by overseeing 90,000 pharmacy practitioners and firms through 12 complex regulatory programs, including enforcement and regulatory issues arising from these programs. The board regulates those who handle, dispense, ship and store prescription drugs and devices to Californians or California health care practitioners.

The Board has over 50 employees statewide including its own in-house staff of inspectors who are pharmacists and authorized officers of the law. These pharmacist inspectors employ their knowledge and expertise of complex pharmacological issues for the investigation of technical practice issues ranging from excessive dispensing, intravenous drug therapy, drug compounding and nuclear pharmacy. The Board's inspectors also work with and assist local law enforcement agencies and state and federal law enforcement agencies in the investigation of violations of pharmacy law. Enforcement is the Board's major public protection priority both in terms of its investigative staff and funding. Enforcement expenditures comprise about 70% of the Board's $8 million annual budget.

Authority for Position

Business and Professions Code, Chapter 9, Division 2, Article 1, section 4003: "The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter..."

Authority of the Executive Officer

Pursuant to California Code of Regulations section 1703, "the power and discretion conferred by law upon the Board to receive and file accusations issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the Board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code.....the certification and delivery or mailing of copies of decisions under Section 11528 of said code; and issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code are...delegated to and conferred upon the executive officer, or in his or her absence, the acting executive officer."

Executive Officer, Board of Pharmacy

The Executive Officer (EO) functions as the Board's chief operating officer and is accountable for the operation and management of all board programs, resources and staff. The EO establishes policies and has decision-making authority over all board operations and delegates operational responsibility to subordinate executive staff and managers.

The EO also functions as the chief advisor and consultant to the Board in the formulation, development, implementation and advocacy of board programs and policies, and strategic plan objectives taking into consideration emerging issues, current statutes, fiscal constraints, staff resources and multiple priorities

Position Description

The EO is the primary point of contact and resource agent for the Board's 13 appointed members and is responsible for interpreting and executing the intent of the Board's policies and for promoting the Board's vision and mission and serves as the Board's liaison with other state and governmental agencies and private agencies. The EO is responsible for providing expertise and direct input to the Board in strategic planning, Board decision making, and in outlining the policy options and their various implications, integrating legal issues, staff resources and public impact. The EO causes the Board to be aware of internal and external factors and considerations that influence Board decisions and policy development.

The EO is accountable for the achievement of the Board's strategic plan and makes decisions that are true to the Board's strategic plan. The EO oversees and manages the Board's five strategic committees – Enforcement, Legislation, Licensing, Communication and Public Education and Organizational Development - having functional responsibility for board programs and broadly organizes, plans and directs work and staff functions so that work necessary to fulfill the Board's consumer protection mandate is performed accurately, timely, legally and efficiently. This is done through licensing, enforcement, organizational performance and administration, communication functions with the public and licensees, and legislative and regulation advocacy.

The EO is responsible for the development and conduct of major studies and special reports detailing specific program areas. These reports include the pharmacy manpower task force recommendations, business process documentation, fee structure analysis, consumer awareness and opinion surveys, strategic plan and business continuity plans and are published and distributed to board members, to executive staff of the Department of Consumer Affairs, to agency representatives, to members of professional associations and other health care agencies, to members of the Legislature and to the public. The EO also ensures the publication and distribution of consumer brochures and Board newsletters. These publications assist California pharmacists and other healthcare providers to be better informed on topics of importance to California patients. The EO is also responsible for the development and presentation of licensee educational programs.

The EO is the bridge between the Board and the Board's staff and leads staff toward the successful accomplishment of Board goals. The Board confines itself to the topmost policy development, leaving implementation and subsidiary policy development and global operational planning to the EO.

Executive Officer, Board of Pharmacy

Duties and Responsibilities

50% Acts as agent, consultant and liaison for the Board of Pharmacy.

- Responsible for understanding, advocating and complying with Board policies and strategic plan objectives. Ensures the development, on-going review and implementation of the strategic plan. Participates in the development of the Board's mission and vision, goals and objectives and strategic performance measures. Assesses Board accomplishments and prepares and presents quarterly strategic plan reports.
- Consults with and provides Board advice on complex legal and regulatory issues involving the practice of pharmacy and emerging issues and serves as consultant to the Board and its policy-development committees on complex policy and program issues. Confers with staff counsel and deputy attorney general liaison on issues requiring policy decisions and legal opinions.
- Coordinates and ensures the execution of all Board and committee meetings, develops Board and committee meeting agendas and acts as Board spokesperson at all meetings and hearings as delegated by the Board. Provides Board with complete, clear and accurate meeting minutes and keeps Board informed of progress of Board programs and issues.
- Acts as the Board's agent and represents the Board in matters before the Legislature, the Governor's Officer, the Department of Consumer Affairs, other state agencies, schools of pharmacy, the media and professional associations. Participates in national and state association meetings.
- Plans and conducts a comprehensive orientation for all new board members.

30% Ensures the effective and efficient management of enforcement programs and the enforcement of Chapter 2, Division 9 of the Business and Professions Code, including the investigation and prosecution of violators.

- Oversees the administration of the various components of the enforcement program to ensure that the public is adequately protected through the inspection of licensed entities, the compliance and education of licensees, the investigation and mediation of alleged violations, the appropriate discipline of licensees, the monitoring of probationers and the referral of pharmacists and interns to the pharmacist recovery program.
- Develops and facilitates critical enforcement statutes, regulations and policies to protect the consumer.
- Ensures that strategic enforcement performance measures are met, reviews investigation reports and authorizes appropriate disciplinary and administrative action. Liaisons with the Board's supervising inspectors in the administration and management of the Board's in-house staff of expert investigative pharmacist inspector teams, comprising of the Drug Diversion/Fraud team, the Pharmacist Recovery Program/Probation team and the Compliance team and works closely with supervising inspectors in the development of the functions and responsibilities of the teams.
- Issues citations and fines and ensures that the citation and fine program is in compliance with its statutory and regulatory mandate.
- Oversees the prosecution of licensees in accordance with the provisions of the Administrative Procedures Acts. Receives, reviews and files accusations, statements of issues and petitions for revocation, determines, negotiates and authorizes appropriate disciplinary penalties in accordance with the Board's penalty guidelines and advises deputy attorneys general of Board policy in disciplinary matters.
- Identifies practice of pharmacy trends such as Internet drug purchasing, compounding drugs, and the purchasing of drugs from foreign countries and determines appropriate enforcement and education actions to safeguard the public.
- Ensures the ongoing review and revision of the Board's penalty guidelines and public disclosure policy.

Executive Officer, Board of Pharmacy

10% Oversees the administration of Examination and Licensing Programs to ensure the professional qualifications of licensees.

- Responsible for ensuring that strategic licensing performance measures are met and that the administration of all licensure activities is completed in an efficient and effective manner.
- Ensures the continuous review and development of pharmacist licensure exams to ensure that they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.
- Responsible to be knowledge of innovative, technological and other pharmacy practices and pharmacological trends to oversee the facilitation of critical statutes, regulations and policies with respect to changes in the pharmacy health care field and corresponding licensing and qualification requirements.

5% Governs the legislative liaison activities of the Board and advocates legislation and regulations that advance the vision and mission of the Board.

- Responsible for the interpretation and execution of Chapter 2, Division 9 of the Business and Professions Code, identifies and responds to legislative changes to keep pharmacy law current and consistent with the Board's strategic plan objectives.
- Identifies the need for new legislation, recommends modifications to existing statutes or regulations to conform to Board policy and to strengthen and enhance the Board's public protection mandate. Ensures the promulgation of regulations in accordance with the provisions and criteria established by the Office of Administrative Law.
- Advocates the Board's position on legislation to senior officials, legislators and the media, oversees the development of legislation and the securing of bill sponsors, approves revisions to pending legislation, secures enactment of Board-sponsored legislation and testifies before legislative committees and public hearings regarding major Board policies, programs and activities.

3% Oversees the achievement of the Board's organizational mission and goals to ensure the efficiency of Board operations.

- Manages a 8 million budget to ensure appropriate allocation of resources to perform mandated Board business and to ensure fiscal viability and program integrity. Oversees executive staff in budget planning and development and ensures that the Board is routinely apprised of the fund condition. Pursues program enhancements and expansions through the budget change proposal process.
- Oversees the strategic planning process through the identification, implementation and continuous assessment of strategic plan objectives and performs strategic management of the Board through all committee and Board activities. Ensures the execution of effective communication venues within the Board structure of executive staff, management staff and inspector staff and analytical and clerical staff.
- Directs the review of workload and resources to streamline operations, target backlogs, and implement program reductions to maximize services and processes while meeting fiscal restraints.
- Ensures the execution of sound personnel practices and procedures in accordance with state personnel rules and the active recruitment, development and evaluation of staff.
- Manages the Sunset Review process, ensures the timely submission of a complete and accurate report to the Joint Legislative Sunset Review Committee and works to secure the passage of legislation to extend the Board's sunset date.

Executive Officer, Board of Pharmacy

2% Provides leadership in the dissemination of relevant information to Board licensees and to the public to provide for improved licensee knowledge and consumer awareness and assures that public outreach and education is implemented as directed by Board committee.

- Manages sensitive Board communications and acts as the Board's spokesperson before legislative committees, agency and departmental staff, other governmental agencies, professional associations, the media, the schools of pharmacy and other interested groups. Ensures the accomplishment of public information requests regarding Board programs, activities and records pursuant to the Public Records Act and the Information Practices Act.
- Serves to educate the licenses and the public through ensuring the accomplishment of the Board's goal to publish and distribute the Board's newsletter *The Script* twice annually and the development and publication of consumer informational brochures.
- Develops Board-sponsored continuing education programs in pharmacy law and coordinates and presents the programs at local and annual professional association meetings throughout California.
- Participates in or delegates appropriate staff to participate in forums, conferences and educational fairs.
- Responsible to ensure the maintenance of the Board's Web site and the integrity of the information presented on the site and, as the Board's custodian of records, ensures the preservation of Board records and certifies as to their accuracy and veracity.

Title 11, Section 703(d) of the California Code of Regulations requires criminal record checks of all personnel who have access to Criminal Offender Record Information (CORI). Pursuant to this requirement, incumbents in this position will be required to submit fingerprints to the Department of Justice and be cleared before hiring.

Rev. 07/03
Rev July 2006

Attachment D

Proposed Agenda for the NABP Districts VII and VIII Meeting

NABP/AACP
District 7 & 8 Meeting

October 4-7, 2006

Disneyland Hotel
Anaheim, CA

TENTATIVE AGENDA

Wednesday, October 4, 2006

5:00 – 8:00 p.m. – Registration Desk Open
6:00 – 8:00 p.m. – Welcome Reception

Thursday, October 5, 2006

7:30 – 8:30 a.m.	(Continental) Breakfast
8:30 – 9:00 a.m.	Welcome and Overview • Bill Powers, President California State Board of Pharmacy • Dean, Western University College of Pharmacy • Lawrence H. Mokhiber, MS, RPh NABP President • Marilyn K. Speedie, PhD AACP 2005-06 President Elect Dean, University of Minnesota College of Pharmacy Welcome to Disneyland – Mickey and Minnie Mouse
9:00 - 10:15 a.m.	Ethics Training Model for Disciplined Pharmacists Lorie Rice, UCSF, School of Pharmacy and Public Member of the Medical Board of California
10:15 – 10:30 a.m.	Break
10:30 – 11:30 a.m.	Pharmacy Practice in Long Term Care Facilities Robert Miller, President American Society of Consultant Pharmacists

11:30 –12:30 p.m. Lunch

12:30 – 1:30 p.m. Medicare Prescription Drug Benefit Plans
Fraud Investigations
Larry Casper, Assistant United States Attorney

1:30 – 3:30 p.m. Internship/Externship Experience
Role of Boards of Pharmacy –
New ACPE Standards – ACPE Speaker
Schools of Pharmacy
Employer
(Panel Discussion after each speaks?)

3:30 p.m. – 3:45 p.m. Break

3:45 p.m. – 5:30 p.m. CONCURRENT SESSIONS

Colleges of Pharmacy – Moderators – XXXX, District 7
XXXX, District 8

Boards of Pharmacy - Moderators – XXXX, District 7
XXXX, District 8

6:30 p.m. Dinner

Friday, October 6, 2006

7:30 – 8:30 a.m. (Continental) Breakfast

8:30 – 9:30 a.m. Medicare Prescription Drug Benefit Plans –
What's New for Year 2?
Lucy Saldana (Invited Representative from CMS)

9:30 – 10:30 a.m. FDA Update on the Prescription Drug Marketing Act

10:30 – 10:45 a.m. Break

10:45 – 11:45 a.m. DEA Update on Pseudoephedrine, Electronic Prescribing, Internet Investigations, NASPAR

11:45 a.m. – 1:00 p.m. Planning for a Pandemic

Afternoon Free

Saturday, October 7, 2006

7:30 – 8:30 a.m. Continental Breakfast

8:30 – 10:00 a.m. **District Business Session**
Treasurer's Reports
Committee Reports

- Election of Officers for each District
- Delegate/Alternate for 2006 NABP Resolutions Committee

Resolution Committee

- Resolutions for the 2007 NABP Annual Meeting

Time and Place Committee

- Meeting Information for the 2007 District 7 & 8 Meeting in Oregon
- 2008 District 7 & 8 Meeting – Announcement of District 8 Host State

Adjourn

Attachment E

Board of Pharmacy Fund Condition

0767 - State Board of Pharmacy
Analysis of Fund Condition

(Dollars In Thousands)

Galley 2 Final (12-12-05) + May Revise

		ACTUAL 2004-05	2005-06	Gov's Budget 2006-07	2007-08	2008-09
BEGINNING BALANCE		$ 4,874	$ 4,111	$ 4,834	$ 4,990	$ 1,985
Prior Year Adjustment		$ 87	$ -	$ -	$ -	$ -
Adjusted Beginning Balance		$ 4,961	$ 4,111	$ 4,834	$ 4,990	$ 1,985
REVENUES AND TRANSFERS						
Revenues:						
125600	Other regulatory fees (REVISED)	$ 422	$ 38	$ 38	$ 38	$ 38
125700	Other regulatory licenses and permits	$ 1,427	$ 1,258	$ 1,243	$ 1,291	$ 1,291
125800	Renewal fees	$ 4,452	$ 4,006	$ 3,977	$ 3,928	$ 3,928
125900	Delinquent fees	$ 81	$ 58	$ 58	$ 58	$ 58
131700	Misc. revenue from local agencies	$ 8	$ -	$ -	$ -	$ -
141200	Sales of documents	$ -	$ -	$ -	$ -	$ -
142500	Miscellaneous services to the public	$ -	$ -	$ -	$ -	$ -
150300	Income from surplus money investments	$ 111	$ 90	$ 40	$ 39	$ -
150500	Interest Income From Interfund Loans	$ -	$ 227	$ -	$ -	$ -
160400	Sale of fixed assets	$ -	$ -	$ -	$ -	$ -
161000	Escheat of unclaimed checks and warrants	$ 4	$ -	$ -	$ -	$ -
161400	Miscellaneous revenues	$ 5	$ -	$ -	$ -	$ -
Totals, Revenues		$ 6,510	$ 5,677	$ 5,356	$ 5,354	$ 5,315
Transfers from Other Funds						
F00001	GF loan per Item 1490-011-0767, BA of 2002	$ -	$ 3,000	$ 3,000	$ -	$ -
F00683	Teale Data Center (CS 15.00, Bud Act of 2005)	$ 8				
Transfers to Other Funds						
T00001	GF loan per Item 1490-011-0767, BA of 2002	$ -	$ -	$ -	$ -	$ -
Totals, Revenues and Transfers		$ 6,518	$ 8,677	$ 8,356	$ 5,354	$ 5,315
Totals, Resources		$ 11,479	$ 12,788	$ 13,190	$ 10,344	$ 7,300
EXPENDITURES						
Disbursements:						
0840 State Controller (State Operations)		$ -	$ -	$ 5	$ -	$ -
1110 Program Expenditures (State Operations) - Galley 2		$ 7,368	$ 7,954	$ 8,195	$ 8,359	$ 8,526
9670 Equity Claims / Board of Control (State Operations)		$ -	$ -	$ -	$ -	$ -
Total Disbursements		$ 7,368	$ 7,954	$ 8,200	$ 8,359	$ 8,526
FUND BALANCE						
Reserve for economic uncertainties		$ 4,111	$ 4,834	$ 4,990	$ 1,985	$ (1,226)
Months in Reserve		6.2	7.1	7.2	2.8	-1.7

NOTES:

A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED

B. EXPENDITURE GROWTH PROJECTED AT 2% BEGINNING FY 2006-07

Attachment F

Board of Pharmacy Members' Submitted Reimbursement and Travel Expenses 2005-2006

Chart 1
Board Member Reimbursement and Expenses
2005/06

Board Member	Hours		Travel	
	Meeting	Other	Expense	Airfare
Marian Balay	59	51	$532.96	$196.10
Richard L. Benson	48	30	$862.82	$920.10
Ruth M. Conroy	48	19	$579.11	$590.80
David J. Fong	67	32	$537.58	$335.00
Stanley Goldenberg	166	75	$1,234.54	$1,299.20
Clarence Hiura	63	56	$1,239.69	$397.20
John D. Jones	106	21	$2,407.24	$2,236.30
William Powers	93	25	$875.60	$533.40
Kenneth H. Schell	32	16	$801.16	$198.40
Andrea Zinder	70	21	$649.55	$409.80
Total	751	345	$9,720.25	$7,116.30

Board member expenses paid from July 1, 2005 to June 30, 2006

Attachment 1

Summary of the Organizational Development Committee Meeting
July 11, 2006

California State Board of Pharmacy
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ORGANIZATIONAL DEVELOPMENT COMMITTEE
Meeting Summary
July 11, 2006
(a non-public meeting)
via teleconference

Present: Ruth Conroy, Board Member and Chair
Bill Powers, Board President
Patricia Harris, Former Executive Officer
Virginia Herold, Acting Executive Officer
Karen Cates, Manager, Enforcement Unit

Chairperson Conroy called the meeting to order at 9:05 a.m.

Plans for Strategic Plan Revision by the Board

The committee discussed plans so that at the July 2006 Board Meeting, the board will complete the 2006/07 revision of its strategic plan.

Ms. Herold noted that during each of the board's committee meetings this quarter, the committees have had the opportunity to make modifications to their committee's strategic plans. All of the board's committees will have done this except for the Legislation and Regulation Committee, which did not have a meeting this quarter.

At the board meeting, each of the committees will seek the board's approval of their committee's plan during the committee report. The Organizational Development Committee report will be the last report at this board meeting, and the entire plan will be adopted at this time.

The committee also reviewed the "Future Vision of Pharmacy Practice" in 2015 as envisioned by the Joint Commission of Pharmacy Practitioners for relevant information about inclusions in the strategic plan.

Plans for Strategic Plan Revision by the Board

The committee reviewed its components of the strategic plan.

Discussion of activities to achieve the committee's objectives occurred, and the plan was approved for review by the board at the July Board Meeting.

Recognition of Pharmacists Who Have Been Licensed 50 Years

Since July 2005, the board has acknowledged 573 pharmacists with 50 or more years of licensure:

July 2005	450 pharmacists
Oct. 2005	50 pharmacists
Jan. 2006	8 pharmacists
April 2006	8 pharmacists
July 2006	57 pharmacists

The pharmacists so honored receive a letter from the board president and a commendation. Each is invited to a future board meeting to be publicly recognized. Additionally, his or her name is published in the board's *The Script.*

Personnel Update and Training Report

- ***Executive Officer Resignation***

On July 1, Executive Officer Harris was appointed as Deputy Director, Bureau Relations in the Department of Consumer Affairs by Governor Schwarzenegger. With this announcement, Ms. Harris resigned as executive officer of the board.

Vice President Ken Schell, acting in the absence of President Bill Powers, appointed Assistant Executive Officer Virginia Herold as acting executive officer until the next meeting of the board. At that meeting, the board will appoint an interim executive officer, until such time as a permanent executive officer can be appointed. This process will likely take three months or more and the Department of Consumer Affairs will provide assistance to the board in this process.

- **Inspector Vacancies, Recruitment and Retention Differential**

The board has lost two inspectors since the April Board meeting:

1. Inspector Jeff Smith, who has been with the board over five years, who was assigned to the drug diversion team and was the board's computer guru, transferred to the Department of Health Services at the beginning of July.
2. Inspector Robert Grimm, who has been with the board for about 10 years on the compliance team transferred to a dispending pharmacist position at a correctional facility in Orange County.

Both inspectors transferred to positions where they will make at least $24,000 more annually than at the board. This salary inequity has been a long standing problem, and the board's staff has recently begun activities to secure a salary adjustment for its pharmacists.

When Inspector Smith resigned at the end of June to transfer to the Department of Health Services, he immediately received an annual salary $24,000 more than at the

board due to a "recruitment and retention differential" paid by some state employers of pharmacists, like the Department of Health Services.

Board staff hope to present a successful case for a similar augment for board inspectors. If approved there will be an annual increase to each inspector and supervising inspector of $24,000 annually, raising inspector salaries to $99,660 and supervising inspector salaries to $103,460. The annual increase from these salaries to the board will be $552,000. Annual salaries of community pharmacists are approximately $110,000 annually.

The board has four inspector vacancies:

- A new, restored position effective 7/1/06
- Jeff Smith's position
- Bob Grimm's position
- Nahal Bahrampour's position (vacant since 3/06)

The board is working with the department's Personnel Office to schedule a new civil service examination from which pharmacists can be hired to work for the board. This process will take at least four more months, and we hope to fill these positions in the fall. This is a priority for the board's senior staff. However, without a salary differential, it will be difficult to recruit quality pharmacists for these important positions.

Dennis Ming, a supervising inspector for the last three years, resigned on June 30, 2006. Dr. Ming was a supervisor of the compliance team. Dr. Ming will remain on the board's staff as a retired annuitant.

The board is also working with the department on a new civil service examination for supervising inspector. Again, this process will likely take four more months and we hope to have this position filled in the fall: this is also a priority for the board's senior staff.

- **Other Staff Changes:**

The board has made several personnel changes since the April meeting:

- Anne Sodergren has become the board's Legislative Manager, replacing Jan Perez whose training and development assignment ended in April.
- Christine Sanchez has joined the board as the new Licensing Unit Manager, replacing Ms. Sodergren. Ms. Sanchez formerly worked for the Womens, Infant and Childrens program in the Department of Health Services.
- Julie Baker has become the board's new receptionist, a position that was restored by the state budget on July 1. Ms. Baker formerly worked for the California Highway Patrol. And in early July, Ms. Baker was appointed to a technician position in the board's executive office where she will eventually replace Candy Place, who will retire in November.
- Nicole Mullnix has joined the board as a part-time receptionist, she formerly worked as a student assistant at the Department of General Services.

The board is recruiting for the following positions:

- A part-time manager/specialist position to serve as coordinator of the Pharmacists Recovery Program.
- An associate analyst to develop consumer and licensee educational materials
- A budget analyst and business position (duties currently performed in part by Ms. Place).
- An enforcement analyst.
- A receptionist to replace Julie Baker
- A seasonal clerk to perform filing and mailing duties.

- **Board Members:**

Ken Schell, PharmD., was appointed July 1 to a second term by Governor Schwarzenegger. Also, Susan Ravnan, PharmD., was appointed July 1 to the union pharmacist member position on the board.

Board Member Marion Balay resigned from the board in May.

The board currently has four public board member positions and two professional member positions vacant. All are governor appointments.

- **Specialized Training:**

All board staff completed a 12-hour, two-day team building training called "colors." The training focuses on individuals' working styles, personality traits and working together.

Board Member Procedure Manual

The committee reviewed the updates to the *Board Member Procedure Manual*. This manual will be submitted to the board for review and approval.

NABP Districts VII and VIII Meeting in California in October

The committee reviewed an agenda developed by Executive Officer Harris, Sam Shimomura and Assistant Executive Officer Harold for this three-day meeting in Anaheim.

Among the topics are:

- a discussion session with the schools and board member attendees on intern experience,
- pandemic planning,
- the new DEA requirements for sales of pseudoephredrine by pharmacies, and
- Medicare Part D Issues.

Registration materials for this meeting should be available for release before mid-August.

The committee noted that the NABP also has formally thanked the board for its hosting of the Hospitality Suite at the May 2006 annual meeting in San Francisco.

Budget Report

- **Report on the 2005/06 Fiscal Year**

  The committee reviewed the budget report. Final figures of revenue and expenditures for the year will not be available until mid-August, so the figures for the year are currently estimates. A final budget report for the year will be provided to the board at the October meeting.

  Revenue Projected: $9,120,296

  This fiscal year the board received repayment of $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund. This repayment is classified as revenue for the year. Three million dollars is still owed to the board from the 2001 loan.

  The board's revenue for the year is projected to be comprised of:

Licensing Fees (estimated):	$5,360,000
Interest	$90,000
General Fund Loan repayment	$3,227,000
Cite & Fine (actual as of 6/30/06)	$273,969
Cost Recovery (actual as of 6/30/06)	169,327
	$9,120,296

  Expenditures Projected: $7,954,121

- **Budget for 2006/07**

  The Board's budget for the fiscal year that started July 1, 2006, is in place.

  Revenue Projected: $8,356,000

  Revenue for this fiscal year is projected to be comprised of $5,316,000 in fees and $40,000 in interest on money in the board's contingency fund. The board is projected to receive the final repayment of $3 million from the 2001 loan of $6 million from the board's fund to the state's General Fund during a period of California's budget crisis.

  Expenditures Projected: $8,446,000

Expenditures for the year are $240,000 more than those projected for the last fiscal year. This increase includes:

-- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000's. ($208,000)
-- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)

The board will receive restoration of one inspector position, one receptionist position and one half-time public outreach position. The receptionist position has been filled, and recruitment is underway for the public outreach position, which will be filled on a full-time basis. The board is commissioning a civil service examination to fill the inspector position.

- **Board Fund Condition**

The board ended the last fiscal year (on June 30, 2006) with a projected reserve of $4,834,000. This is 7.1 months of expenditures

The board's fund condition projections over the next few years (as estimated in early May 2006) are:

- 2006-07: A reserve of 7.2 months is projected.
- 2007-08: A reserve of 2.8 months is projected.
- 2008-09: A deficit in the reserve of is projected of –1.7 months

A fee increase may be needed to take effect July 1, 2008 to prevent a deficit during 2008-09. Board staff will continue to watch these figures closely.

I-Licensing Progress

Ms. Herold noted that the DCA is now moving ahead with a proposal so interested agencies can offer online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future.

A budget change proposal will need to be written and approved for the board to participate in this project in the future as well. The DCA will be developing this budget change proposal for all participating agencies.

No costs are yet available for this conversion, and it will be at least one year from implementation at the board.

Proposed Meeting Dates for 2007

The committee agreed to a staff proposal to move the July 2007 board meeting, which has traditionally been in San Diego, to another location (to switch the location with January board meeting which is usually scheduled for LA/Orange County).

Ms. Herold explained that for the last two years, trying to arrange a board meeting in July in San Diego has been difficult and expensive. As a resort community, the areas downtown (that are near the airport) are very expensive during the summer. For example, this year, an overnight room at a downtown hotel is well over $250 and in some hotels exceeds $300. Had the 2006 board meeting been in San Diego as initially scheduled, the cost of the meeting room with the necessary sound system would have exceeded $7,300, and each overnight room would have been $175.

The proposed board meeting dates and locations are:

2006

- October 25 and 26 – San Francisco/Bay Area *(CSHP's Seminar is in Sacramento on Oct 12-15)*

2007

- January 31 and February 1 -- San Diego *(CPhA's Outlook is February 15-18 in Palm Springs)*
- April 18, 19 – Sacramento *(NABP's Annual Meeting is in Portland Oregon in May)*
- July 25, 26 – Los Angeles/Orange County
- October 24 and 25 -- San Francisco/Bay Area *(CSHP's Seminar is October 18-21 in Palm Springs*

Executive Officer Recruitment

Note: Ms. Herold recused herself from this discussion and left the meeting room.

Staff of the Department of Consumer Affairs' Personnel Office met with the Organizational Development Committee to provide an overview of a recommended process for selection of the executive officer.

Staff from the Personnel Office will attend the board meeting to provide information and assist the board in this process.

Adjournment

There being no additional business, the committee meeting was adjourned at 10:40 a.m.

Strategic Plan Status Report
Fourth Quarter 2005/2006
April 1, 2006 through June 30, 2006

Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.** **Outcome:** An effective organization
Objective 5.1:	**Obtain 100 percent approval for identified program needs by June 30, 2006.** **Measure:** Percentage approved for identified program needs
Tasks:	**1. Review workload and resources to streamline operations, target backlogs and maximize services.** **October 2003:** ▪ Board implements and identifies a number of legislative and regulatory proposals to streamline applications and application processing, complaint resolution and investigation procedures. These include: ▪ Citations and fines being issued by the executive officer instead of a committee of the board. ▪ New requirements enacted for pharmacy technicians and use of NAPLEX exam. ▪ Status calls on applications pending less than 8 weeks are not answered. ▪ Processing of fingerprint clearances and conviction information altered. ▪ Statutory or regulation changes proposed for applicants for pharmacist, pharmacy technicians, interns, wholesalers and non-resident wholesalers. ▪ All Sacramento staff assigned to cover phones as routine duties ▪ Board's Web site will be revamped to make information more accessible. ▪ Enforcement actions against licensees will be integrated into the License Verification function of the Web page to facilitate disclosure of information to the public. **January 2004**: ▪ Board modifies procedures for processing pharmacy technicians so that all information required to make a licensing decision is submitted at one time (previously the various required components could each be submitted at any time, creating a substantial workload to match information to files.). The goal is to reduce the volume of individual pieces of application information that are submitted at different times. ▪ All staff are assigned to answer phones in four-hour blocks to fill behind the board's part-time receptionists and still provide phone coverage for the public. The telephone tree is redesigned to place calls immediately on hold, without the direct intervention of a board operator. ▪ Address of record information was placed online in mid-December. This eliminates the need for staff to provide this publicly releasable information. ▪ Enforcement information will be soon added to the Web site so complete license verification information will be available on the Web site. ▪ Board procedures for issuing citations and fines and changed to make it easier to respond to public inquiries. ▪ Data systems for monitoring enforcement cases assigned to board staff are integrated so that only one report is prepared monthly instead of two.

March 2004

- Contracts for CPJE in place; board begins notification of candidates for pharmacist licensure they may take CPJE examination. Over 750 applications processed by end of month.
- Board seeks subscriber service to board's Web site as a possible means for future communication with licensees, applicants and the public.

April 2004:

- Pilot testing of Web site enforcement look up completed and process made available online.
- NAPLEX available to California applicants for pharmacist licensure.
- Security processes for data transfer among entities providing examination services under development.

June 2004:

- Exam scores released and licensure of new pharmacist begins under new examination structure

October 2004:

- Staff identifies a number of legislative and regulatory proposals to streamline applications and application processing, complaint resolution and investigation procedures in the future. These are brought to the board for pursuit as regulations or statutory changes.
- Subscriber alert feature added to board Web site to alert interested parties about new items placed on the Web site.

November 2004:

- Board modifies application procedures for wholesalers and nonresident wholesalers, designated representatives and pharmacy interns.

December 2004:

- New board contracts established for NAPLEX and CPJE exam administrations.
- New Web site activated that is compliant with Governor's Office requirements

January 2005:

- Board acts on a omnibus package of regulation changes to update board regulatory programs affected by enactment of SB 361, SB 151, and SB 1913. Provisions for omnibus legislative changes are submitted to Legislative Counsel.

October 2005:

- Board omnibus legislation enacted as SB 1111. Board rulemaking containing numerous provisions to streamline operations or make consistent with law takes effect October 7.

January 2006:

- Board continues adjustments to operations following its move to new location in December. The new phone system will be modified to improve service to callers.

April 2006:

- Service order to modify phone system submitted.
- New procedures to standardize clinic applications submitted as part of board omnibus provisions for 2006.
- Enforcement coordinator designated with responsibility to review criminal convictions and other enforcement matters, rerouting work from the enforcement manager.
- Altered means for technician applicants to request status checks regarding their applications from a telephone system to an e-mail system, substantially reducing telephone calls to the technician processing desk.
- Implemented new statutory provisions that pharmacists who fail to certify their CE on renewal applications are now renewed as inactive.

June 2006:

- Backlogs of up to six weeks in board receipt of cashiering records and materials from DCA have negatively impacted the work of board cashiers and are preventing

	accurate renewal information from appearing online. Board managers continue to contact DCA administrators and managers for intervention. ▪ Board continues to wait for modifications to the telephone system that will aid callers in getting to the right individual without waiting in a lengthy que. ▪ Enforcement actions and lookup of recently taken disciplinary actions put online.
Task:	**2. Develop budget change proposals to secure funding for needed resources.** **August 2003:** ▪ Budget instructions from Department of Finance specify that no program augmentations will be made this year; any increase in resources must come via redirection from within an agency's budget. As such the board dissolves plans for BCPs to augment AG resources and fund a job analysis. **August 2004**: ▪ Budget instructions from Department of Finance specify that no program augmentations will be made this year; any increase in resources must come via redirection from within an agency's budget. As such the board dissolves plans for BCPs to augment AG resources and fund a job analysis. Legislative BCP for SB 1307 and AB 2682 to provide $85,000 for programming modifications to the board's wholesaler programs are denied; the board must redirect to cover from existing programs to fund these costs. **March 2005:** ▪ Concept paper submitted for proposed staff augmentation for the 2006-07 fiscal year. **June 2005:** ▪ Budget change proposals submitted for proposed staff augmentation for the 2006-07 fiscal year. **September 2005:** ▪ Budget change proposals submitted to the Administration for the 2006-07 fiscal year. **January 2006:** ▪ Board continues adjustments to operations following move to new location in December. The new phone system will be modified to improve service to callers. ▪ Governor's Proposed Budget for 2006/07 contains restoration of 2.5 positions lost during the prior four years of hiring freezes. One inspector, one receptionist and one-half position for public outreach are proposed. Another $96,000 is proposed to cover an hourly increase in AG expenses to $158 effective 7/1/06. **April 2006** ▪ Concept paper submitted for staff augmentations for 2007/08. **June 2006** ▪ BCP submitted to department for staff augmentations for 2007/08
Task:	**3. Perform strategic management of the board through all committees and board activities.** **October 2003:** ▪ Strategic plan updates from all committees provided to board for review during board meeting. **January 2004**: ▪ Strategic plan updates from all committees provide to board for review during board meeting. Additionally committee readies plan for 2004 update of board strategic plan, planned for the April 2004 meeting. **April 2004:** ▪ Strategic plan for each committee and overall plan for the board reviewed and approved by board for 2005.

	July 2004: ▪ Strategic plan updates from all committees provided to board for review during board meeting. The cost of prescription drugs section of the Strategic Issues to be Addressed chapter is revised and approved by the board for inclusion in the strategic plan. **October 2004:** ▪ Strategic plan updates from all committees provided to board for review during board meeting. In advance of the board meeting, each committee holds a public meeting; one topic discussed at each meeting is how to increase communication between the board and the public and licensees. **January 2005**: ▪ Strategic plan updates from all committees provided to board for review during board meeting. Committee begins plans to revise strategic plan at the April Board Meeting. **April 2005** ▪ Strategic plan update from all board committees provided to board for review during board meeting. Board reviews, modifies and adopts plan for 2005-06. **July 2005**: ▪ Strategic plan updates from all committees provided to the board for review during the July Board Meeting. **September 2005:** ▪ Board hires a consultant to lead board in developing the 2006-2011 strategic plan. **October 2005:** ▪ Strategic plan updates from all committees provided to the board for review during the October Board Meeting. **January 2006:** ▪ Strategic plan updates from all committees provided to the board for review during the January Board Meeting. ▪ Preparations continue for strategic plan update scheduled for the April 2006 Meeting. **March 2006:** ▪ Committee meets twice to prepare for strategic plan update for the April Board Meeting. A stakeholder survey was mailed and placed online to interested parties. ▪ All board staff participate in review of strategic issues, goals, and results of stakeholders' surveys. **April 2006:** ▪ Board initiates strategic plan review at its April 2006 Meeting. ▪ Strategic plan updates from all committees provided to the board for review during the April Board Meeting. **June & July 2006:** ▪ Each committee reviews and modifies its objectives and activities for the 2006/07 plan. ▪ Strategic plan updates from all committees provided to the board for review during the July Board Meeting. ▪ Ratification of the medications to the strategic plan initiated since March occurs by the board during the July Board Meeting.
Task:	**4. Manage the board's financial resources to ensure fiscal viability and program integrity.** **October 2003:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. **January 2004:**

	▪ Budget report provided to board on fund condition, revenue, expenditures and mandatory budget reductions. **April 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. Board pursues departmental assistance for a funding augmentation for 2004/05 for legal services from the Attorney General's Office to retain same level of service at higher fee rates now in effect by the AG's staff. **July 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. Board receives notification it will receive a $135,000 funding augmentation for 2004/05 for legal services from the Attorney General's Office to retain same level of service at higher fee rates now in effect by the AG's staff. **September 2004:** ▪ Committee reviews full budget report on 2003/04 and future year budgets Board receives augmentation in AG budget of $216,000 to adjust for higher hourly rates charged by the AG's Office **October 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. **January 2005:** ▪ Full budget report provided to board on fund condition, revenue and expenditures. **April 2005:** ▪ Full budget report provided to board on fund condition, revenue and expenditures. **July 2005**: ▪ Full budget report provided to the board on fund condition revenue and expenditures. ▪ Board receives a $3.2 million repayment of the 2001 loan to the state's General Fund as an augmentation to its revenue to forestall a possible fund deficit. Two hundred thousand of this is interest. **October 2005**: ▪ Full budget report provided to board on fund condition, revenue and expenditures for 2004/05 and 2005/06 **January 2006**: ▪ Full budget report provided to board on fund condition, revenue and expenditures. **April 2006:** ▪ Full budget report provided to board on fund condition, revenue and expenditures. **June and July 2006:** ▪ Full budget report provided to board on fund condition, revenue and expenditures for 2005/06 and 2006/07.
Objective 5.2:	**Maintain 100 percent staffing of all board positions.** **Measure:** Percentage staffing of board positions.
Tasks:	**1. Continue active recruitment of pharmacists for inspector positions.** **July 2003**: ▪ Three vacant inspector positions lost due to executive order mandating elimination of any position vacant on June 30, 2003 **September 2003**: ▪ Department of Consumer Affairs notifies board that it is discontinuing the continuous application process for board inspector positions. The board has no vacant inspector positions and DCA can no longer dedicate staff to this function

without a corresponding need by the board to have the civil service exam given.

January 2004:

- Two inspectors on parental leave; however the board has no vacancies. Board requests the department to give an annual inspector exam so that the civil service list for this classification remains active.

February 2004:

- One inspector formerly on parental leave resigns from board. Board seeks recruitment of pharmacists from other state agencies on layoff lists. No such pharmacists exist, and the board submits a freeze exemption to fill the position.

April 2004:

- One inspector on parental leave. Freeze waiver for one vacant inspector position undergoing review by the Department of Finance.

June 2004:

- Hiring freeze ends at end of fiscal year. Board initiates actions to fill vacant inspector position. Board also seeks recruitment of pharmacists from other state agencies. No one responds to position.

August 2004:

- Pharmacists contacted on inspector civil service list to determine their interest in working for board. The board is not interested in those who respond. Board again requests department to give a new civil service examination for the classification.

September2004:

- Board again requests the inspector exam. Board increases time base of one part-time inspector from 50 percent to 75 percent of one full-time position.

November 2004:

- Board completes job analysis on inspector position.

December 2004:

- Department sets date for examination.

March 11, 2005:

- Final filing date for inspector classification. Resignation of one inspector leaves two inspector positions vacant. Interview date set for inspector classification interviews.

May 2005:

- Interviews conducted for inspector classification

June 2005:

- Resignation of one inspector leaves two positions vacant.

August 2005:

- Interviews of inspector applicants conducted.

October 2005:

- Three inspectors hired, leaving no inspector positions vacant. Board requests development of new inspector exam from the department.

January 2006:

- All inspector positions filled. Board anticipates restoration via the 2006/07 budget lost during hiring freezes over the prior five years.

March 2006:

- Resignation of one inspector and restoration of one inspector position effective 7/1/06 with the new budget mean that the board must develop a new civil service list for the inspector classification. The Department of Consumer Affairs cannot schedule this exam until the next fiscal year.
- Planned resignation of one supervising inspector effective 7/1/06 means that the board must also develop a new civil service list for the supervising inspector classification. The Department of Consumer Affairs states that it cannot schedule this exam until the next fiscal year.

April 2006:

- Appeal by the board leads the Department of Consumer Affairs to work with the board to reschedule the two examinations earlier that the department initially agreed.

	No date yet set for these examinations. **June & July 2006:** ▪ Three inspectors have transferred from the board in the last 3 months, and one inspector position was restored with the new budget on July 1. The board has four inspector vacancies and 1 supervising inspector vacancies. ▪ The board begins work with DCA on development of a job analysis for both the inspector and supervising inspector classifications, a precursor to having a civil service examination. ▪ Staff begin salary augmentation requests for the board's pharmacists, to eliminate a huge disparity between salaries paid to other state and private pharmacists.
Task:	**2. Vigorously recruit for any vacant positions.** **July 2003**: ▪ Six vacant positions lost due to executive order mandating elimination of any position vacant on June 30, 2003 – three inspector positions, one receptionist, one office technician for site licensing, one associate analyst for site licensing. As a result, the board has no vacant positions. **January 2004**: ▪ The board has no vacant positions. **April 2004:** ▪ The board is seeking a freeze exemption for its vacant inspector position. **June 2004**: ▪ Freeze waiver not processed by the Department of Finance because freeze will end June 30. Board begins recruitment for vacant inspector position, and to hire seasonal staff. **July 2004:** ▪ Board begins recruitment for vacant office technician position. **August 2004**: ▪ Budget Letter indicates process to reinstate positions lost due to hiring freeze; however, implementation of the requirements require that only positions lost in 2003/04 qualify. The board did not lose any positions during this year; however, six vacant positions were lost due to executive order mandating elimination of any position vacant on June 30, 2003, and four were lost in June of 2002. Board seeks to hire temporary staff – two seasonals, and one retired annuitant. One part-time OT leaves board employment. **September 2004**: ▪ Board hires two seasonal staff and rehires its former newsletter editor as a retired annuitant. Board conducts interviews for office technician position. **October 2004**: ▪ Board hires office technician for cashier position. Board begins recruitment for vacant legislative position. One seasonal staff quits. **January 2005:** ▪ Board hires new legislative coordinator and one temporary clerical employee. Recruitment continues for another temporary clerical position. **February 2005.** ▪ Second part-time and temporary receptionist hired. One additional seasonal employee hired to aid in reducing miscellaneous filing backlogs and clerical duties. **July 2005:** ▪ One office technician resigns to accept a promotion at another agency. Recruitment begins to fill this position. **October 2005**: ▪ OT for exam desk filled, new PI receptionist hired, pending retirement of SSA is

	filled early for training purposes, recruitment begins for new MST for wholesaler application processing. Recruitment also underway for new SSA. **January 2006**: ▪ Additional PI hired to perform receptionist duties. Recruitment underway for an associate analyst for computer operations, an analyst for complaint mediation and a technician for application processing. **April 2006:** ▪ Board makes a number of changes in staffing for operational needs and staff development. New analyst hired for enforcement program, Web site duties and computer support functions provided to existing staff. Existing staff redirected to perform enforcement or licensing functions. Board promotes temporary staff into cashier position, and makes hiring commitments for licensing unit manager and legislative coordinator positions. Recruitment underway for a new office supervisor over the licensing unit staff and to provide backup to eliminate backlogs. Recruitment also underway for a file clerk and full-time receptionist. Board receives approval for a temporary, half-time manager position to oversee the Pharmacists Recovery Program. Recruitment underway. **June & July 2006:** ▪ EO Harris resigns, and AEO Herold appointed as acting EO, pending recruitment and action by the board to hire a new EO ▪ Board hires new licensing unit manager, new receptionist and transfers a manager into the legislative specialist position. New clerk hired for receptionist duties ▪ Board transfers staff to fill MST position in the executive officer. ▪ Recruitment for public outreach, budget analyst, receptionist and two enforcement staff underway.
Task:	**3. Perform annual performance and training assessments of all staff.** **December 2003:** ▪ All inspectors have annual performance assessments done by their supervisors. State budget restrictions on training may impede the ability of the board to provide all training needed or desired by inspectors. **December 2004:** ▪ All licensing staff and most inspectors have annual assessments. The remaining assessments will be conducted in the next few months. **April 2006:** ▪ All staff will have annual assessments by Sept 1. **July 2006:** ▪ All inspectors have annual assessments completed.
Objective 5.3:	**Implement 10 strategic initiatives to automate board processes by June 30, 2006.** **Measure:** Number of strategic initiatives implemented to automate board processes.
Task:	**1. Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities.** **July 2003:** ▪ Department of Finance issues budget instructions stating all computer installation projects and proposals are postponed due to budget crisis. ▪ Continue to work with the Department on the development and implementation of the Professional Licensing and Enforcement Management System (PLEMS).

	November 2003: ▪ Department of Finance denies Department of Consumer Affairs' PLEMS feasibility study report. Department discontinues project. Board suggests reassignment of existing information technology staff to resume programming modifications to existing CAS system which were reassigned to develop PLEMS. This will prevent board from realizing one finding of DCA's Internal Audits Office – to have only one tracking system in place at the board. **May 2004:** ▪ Board prepares parameters to join DCA's applicant tracking system to eventually enable online renewals in the future. **April 2005:** ▪ Board in first tier of agencies implementing applicant tracking. Implementation is still at least one year away. **June 2005:** ▪ Staff meets with DCA information specialists to discuss feasibility of working with CPhA on a joint information technology platform to allow e-mail addresses and online renewals. Technology, cost and legal issues will need research. **July 2005**: ▪ Board now in second tier of agencies implementing application tracking, where conversion will begin about January 2006. Meanwhile DCA is exploring online renewal for all departmental entities, possibly for a BCP for 2006-07. **August 2005:** ▪ Board EO signs on as executive sponsor of I-licensing project for the department. Staff participate in review of vendor software and systems to permit license renewal online. **January 2006:** ▪ FSR for I-Licensing project approved that will allow online license renewal. The board is in first tier for implementation which is at least one year away. ▪ Staff continues work needed for automated application tracking. **April 2006:** ▪ FSR for I-Licensing project approved; this will allow online license renewal and application submission. The board is in first tier for implementation which is at least two years away. The Department of Finance directed in March that all work stop on this project until funding is approved (budget year 2006/07). ▪ Staff continues work needed for automated application tracking, the precursor to I-Licensing. **June & July 2006:** ▪ DCA authorized to proceed with I-Licensing. Acting EO agrees to resume former EO's duties as executive sponsor. New budget for 2006/07 authorizes DCA to proceed. ▪ Automated applicant tracking delayed until November 1 at request of DCA.
Task:	**2. CURES** **November 2003**: ▪ Board Inspector develops program to integrate CURES data into board's pharmacy inspection tracking program, so that summary CURES data is immediately retrievable when looking at a pharmacy's record. **January 2005**: ▪ Board approves $24,000 one-time annual increase in funding for CURES, at the request of the Department of Justice, for a total annual amount of $92,000 for contract services. **April 2005**: ▪ New operating system for CURES online. Board staff working to learn new system.

	List of problems and training issues begins being targeted for resolution. **July 2005**: ▪ The board's share of the CURES funding remains at $92,000 for 2005/06 **September 2005:** ▪ Preliminary steps underway to initiate FSR for online, real-time processing of controlled substances as provided by SB 734 (Torlakson) **January 2006:** ▪ Staff agrees to assist in a UCD Med. Center Study regarding implementation of a security prescription forms in California. ▪ Board is waiting for DOJ to write the FSR required by SB 734. **April 2006:** ▪ The proposed UCD Med. Center Study regarding implementation of a security prescription forms in California was not funded. ▪ Board is waiting for DOJ to write the FSR required by SB 734. ▪ DOJ sponsors legislative proposal to require weekly submission of CURES data and to add Schedule IV prescriptions to the tracking system. **June and July 2006:** ▪ Board is waiting for DOJ to write the FSR required by SB 734. ▪ DOJ legislative proposal to require weekly submission of CURES data and to add Schedule IV prescriptions to the tracking system continues in Legislature
Tasks:	**3. Board seeks software to allow subscribers to the board's Web site to be notified when the Web site is updated.** **September 2004:** ▪ Board pilot tests system **October 2004**: ▪ Board activates system **October 2005**: ▪ More than 1,800 individuals are part of the board's subscriber system. **April 2006:** ▪ More than 2,350 individuals are part of the board's subscriber system. **June & July 2006:** ▪ More than 2,400 individuals are part of the board's subscriber system.
Task:	**4. Miscellaneous Projects** **January 2004**: ▪ Board purchases new printers for board office to provide more efficient use of board's new file server. **May 2004**: ▪ Board meets with department's OIS staff on board strategic priorities for automation. The need to allow online renewal is the board's #1 priority. The board stated its desire for online submission of applications, an automated tracking system (PLEMS) and the ability of applicants to identify the status of their applications online. **June 2005**: ▪ Tracking systems for enforcement case management under development. **September 2005**: ▪ In-house program developed to track probationers and PRP participants by inspectors in the field. **January 2006:**

	▪ Testing is nearly complete on the PRP/probationer log. ▪ Staff develops training segments that pop up on specific lap top functions used by inspectors. **April 2006:** ▪ Testing continues on the PRP/probationer log; data being entered into system. Staff training planned for this summer. **Junel 2006:** ▪ PRP/probationer log provided to inspectors after providing staff training. Field testing of the system is now underway.
Task:	**5. Pharmacist Licensure Examinations:** **March –June 2004:** ▪ New and secured systems developed to transmit data to and from vendors of the NAPLEX and CPJE exams, provide results to candidates in an automated fashion as much as possible. **September – October 2005:** ▪ Quality assurance review underway, CPJE results held until completion. **November 2005:** ▪ Board completes quality assurance review and releases results. **April 2006:** ▪ New content outline for exam implemented ▪ New *Candidates Guide* developed and put online. New sample test questions, once used on the CPJE have been added to the guide and online to provide candidates with experience with the type of questions asked. ▪ Board initiates new quality assurance review; CPJE results will be held until completion. **July 2006:** ▪ Quality assurance review, established April 1, remains in effect as fewer than 160 individuals take the CPJE between April 1 and July 1.
Objective 5.4:	**Provide for communication venues to communicate within the board by June 30, 2005.** **Measure:** Number of communication venues to communicate within the board
Task:	1. **Continue the Communication Team to improve communication among staff and host quarterly staff meetings.**

July 2003:

- Quarterly staff meeting made discretionary for board inspectors due to lack of a state budget. TCT hosts annual picnic for all Sacramento staff and a number of inspectors who travel to Sacramento.

September 2003:

- TCT conducts mail-ballot election to replace vacancy of one analyst on the TCT

October 2003:

- To reduce travel expenses, quarterly staff meetings are converted to biannual meetings (July and December), as such no TCT quarterly meeting held.

December 2003:

- TCT hosts staff meeting and team building activities for all board staff. Board members provide Christmas lunch to staff.

March 2004:

- LA-based inspector staff attend Enforcement Team Meeting in Burbank.

May 2004:

- Inspectors hold inspector workshop in Fresno

June 2004:

- TCT hosts staff meeting and annual staff picnic
- Sacramento-based inspector staff join other Sacramento staff to attend Enforcement Team Meeting

September 2004:

- LA-based inspector staff attend Enforcement Team Meeting in Burbank

October 2004:

- Team meetings of each inspector team occur in Sacramento during time of new equipment exchange

December 2004:

- TCT hosts staff meeting. Board members provide a Holiday lunch for staff.

June 2005:

- TCT hosts staff meeting and annual staff picnic.

July-October 2005:

- TCT conducts fundraising for holiday party and begins planning for December meeting.

December 2005:

- TCT hosts staff meeting.

March 2006:

- Staff participate in strategic planning session

June 2006:

- All staff participate in 12-hour team building training called "Colors."
- TCT hosts staff meeting
- TCT hosts annual staff picnic.

Task:	**2. Continue Enforcement Team meetings with board members and enforcement staff.** **July 2003:** ▪ Enforcement team meeting held in Sacramento. To reduce travel expenses, quarterly team meetings with all enforcement staff will be converted to biannual meetings. Supervising inspectors will provide inspector meetings to update Los Angeles-based staff. **September 2003:** ▪ Enforcement team meeting held in Sacramento. Los Angeles inspectors not present, but supervisors hold inspector meeting in LA for these staff to reduce travel expenses. **December 2003**: ▪ Enforcement Committee and Enforcement Team meetings held with all board enforcement staff. **March 2004**: ▪ LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting. **June 2004**: ▪ Enforcement team meeting in Sacramento. Los Angeles inspectors not present **September 2004:** ▪ LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting. **December 2004**: ▪ Enforcement Team Meeting in Sacramento. **March 2005**: ▪ Southern California inspectors meet as Enforcement Team in Burbank in conjunction with Enforcement Committee Meeting. **June 2005:** ▪ Enforcement team meeting in Sacramento with all enforcement staff statewide. **December 2005:** ▪ No team meeting convened due to board's imminent move. **April 2006:** ▪ All inspectors participate in 40day intensive writing course in Sacramento. **June 2006:** ▪ Inspector meeting occurs.
Task:	**3. Convene inspector meetings to develop standardized investigation and inspection processes and earn continuing education.** **July 2003**: ▪ Inspector meeting held in conjunction with Enforcement Team meeting. **September 2003:** ▪ Inspector meeting held in Northern and Southern CA. Topics include development of new procedures, case presentation and review, and workload discussions. **December 2003**: ▪ Inspector meeting held with all inspectors. Computer modifications incorporated onto all inspectors' computers. **March 2004:** ▪ Inspector meeting planned for late May to focus on improving investigation reports. **May 2004:** ▪ Inspectors hold four-day inspector workshop in Fresno to provide training and discussion of investigations. **June 2004:**

	▪ Inspectors have one-day inspector meeting as part of semi-annual meetings. **August 2004**: ▪ Compliance team inspectors meet to identify and assign inspection locations through June 2005 **October 2004**: ▪ All inspector teams meet during reassignment of equipment **December 2004:** ▪ All inspectors trained in new Pharmacy Law provisions for 2005. **March 2005:** ▪ Drug diversion inspector team undergoes training for inspecting wholesaler facilities. **June 2005**: ▪ All inspectors attend inspectors meeting that focuses on new activity reporting system and use of Garmins for directions. **November 2005:** ▪ Three-Day Inspector workshop held in San Diego. **December 2005:** ▪ Inspector meeting held to discuss new laws and regulations. **March 2006** ▪ Drug Diversion and Fraud Team inspectors and other inspectors attend Work Group on Implementing the Drug Pedigree Meeting in Sacramento. **April 2006:** ▪ All inspectors attend four-day writing class along with certain other staff. **June 2006:** ▪ All inspectors attend ePedigree meeting with stakeholders.
Objective 5.5:	**Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed.** **Measure:** Number of outreach programs conducted in one year
Task:	**1. Attend outreach programs.** **September 2003**: ▪ President Jones attends NABP's District VII and VIII meeting **October 2003:** ▪ Board participates in CSHP's Annual Seminar in Sacramento **November 2003:** ▪ Board participates in development of Emergency Contraception Protocol for pharmacists, as required by SB 490 (Alpert, Chapter 651, Statutes of 2003) **December 2003:** ▪ Staff attend USC Seminar in Balancing the Rx Cost/Benefit Equation **January 2004**: ▪ Board participates in CPhA's Outlook 2004 **March 2004**: ▪ Board convenes Workgroup on Pharmacy Compounding task force to determine parameters for distinguishing between compounding and manufacturing **April 2004:** ▪ Board members attend NABP's annual meeting. **June 2004:** ▪ Board participates in public policy discussion regarding importation of Canadian drugs hosted by the Pharmacy Foundation of California. Board holds second meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing. **September 2004**:

- Board holds third meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing.

October 2004:

- Executive Officer attends Clearinghouse on Licensure and Enforcement Regulator (CLEAR) in Kansas City, she provides a presentation on doing more with less.

November 2004:

- Supervising Inspector Ratcliff is keynote speaker at CSHP's annual meeting. Also, Board President Goldenberg and Supervising Inspector Ming provide presentations about the board and sterile injectable compounding.

December 2004:

- Board holds fourth and final meeting of Workgroup on Pharmacy Compounding to determine parameters for compounding pharmacies.

January 2005:

- Staff begin participation with the NABP on implementing radio frequency identification technology.

March 2005:

- Board staff begin participation on two multi-agency work groups to develop pharmacy response teams to respond to natural disasters and declared emergencies.

April, May, June 2005:

- Staff attend multi-agency work groups to develop pharmacy response teams to respond to natural disasters and declared emergencies. Also, conference calls continue regarding implementation of radio frequency identification technology.

July 2005:

- Board convenes Subcommittee on Medicare Prescription Drug Plans to discuss the coming changes in prescription drug coverage for Medicare- and Medicaid-covered.

September 2005:

- Board participates in meeting of Northern California Pain Initiative.

October 2005:

- Second meeting of Subcommittee on Medicare Prescription Drug Plans
- Executive Officer and board members attend NABP District VII and VIII meeting.
- Board President participates in NABP Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Part D.
- Board continues to participate with the group implementing nonprescription syringe sales in specific counties.

December 2005:

- Board initiates Workgroup on Pedigree Implementation to discuss issues involving the 1/1/07 requirement that all medication have a pedigree from manufacturer to wholesaler.

January 2006:

- Board holds third subcommittee meeting on Implementation of the Medicare Plan D Benefit.
- Staff attends Northern California pain initiative meeting.

February 2006:

- Executive Officer provides presentation at the Federation of Associations of Regulatory Boards annual meeting on "Board Governance: A Panel Discussion on the Pros and Cons of Different Board Structures." She also participates in a panel discussion on alternative enforcement models.
- Supervising Inspector Nurse provided a PowerPoint presentation via teleconference to an FDA Counterfeiting Task Force in Bethesda, MD.
- Supervising Inspector Ming provides information about sterile injectable compounding requirements to the Respiratory Care Examining Committee.

March 2006:

- Staff attends meeting coordinated by the DHS Office of AIDS to implement SB 1159, allowing pharmacies to sell 10 needles and syringes without a prescription as

	a means to reduce the spread of Hepatitis C and HIV. ▪ Board convenes the Workgroup on Pedigree Implementation to discuss issues involving the 1/1/07 requirement that all medication have a pedigree from manufacturer to wholesaler. A large number of interested parties attend. **April 2006:** ▪ Board holds fourth subcommittee meeting on Implementation of the Medicare Plan D Benefit. ▪ Board President Goldenberg provides welcoming remarks to the opening session of the National Association of Boards of Pharmacy Annual Meeting in San Francisco. Other board presentations at this annual meeting included moderation of a panel discussion by Executive Officer Harris on emergency preparedness. Because this meeting was in San Francisco, a number of board members and staff attend. **May 2006:** ▪ Board VP, EO and AEO attend policy workgroup session on Implementation of the Medicare Plan D Benefit hosted by the California Pharmacy Foundation. CMS, health care plans and other regulators attend. ▪ EO provides presentation at DCA's Senior Summit. **June 2006:** ▪ Board hosts second ePedigree Work group meeting. ▪ EO attends high level policy meeting were pandemic planning is discussed ▪ Board Member attends planning session identifying which individuals should receive immunizations first in the event of a pandemic. ▪ Board holds fifth subcommittee meeting on Implementation of the Medicare Plan D Benefit.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: **April 26 and 27, 2006**

LOCATION:

April 26, 2006
Red Lion Hotel
1401 Arden Way
Sacramento, CA

April 27, 2006
Department of Consumer Affairs
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

BOARD MEMBERS PRESENT:

Stanley Goldenberg, President
William Powers, Vice President
Marian Balay
Richard Benson
Ruth Conroy
David Fong
Clarence Hiura
John Jones
Kenneth Schell
Andrea Zinder

STAFF PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
LaVonne Powell, Department of Consumer Affairs Legal Counsel
Jan Perez, Legislative Coordinator

CALL TO ORDER

President Goldenberg called the meeting to order at 8:34 a.m. on April 26, 2006.

PRESIDENT'S REPORT

President Goldenberg acknowledged former board president Richard Mazzoni who was in the audience.

President Goldenberg acknowledged Oren Peacock, recently elected as President of the National Association of Boards of Pharmacy, who was in the audience.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

- **Report on the April 2006 Meeting**

Chairperson Conroy stated that the Organizational Development Committee met twice in nonpublic, teleconferenced meetings since the February 1 and 2, 2006 Board Meeting.

1. On March 1, the committee met to discuss the board's update to the strategic plan.
2. On April 6, the committee met to discuss the board's update to the strategic plan and to discuss the normal business of the committee.

Chairperson Conroy stated that later during this board meeting, the board will work in public session with Lindle Hatton, PhD, on updating the board's strategic plan.

- **Recognition of Pharmacists Who Have Been Licensed for 50 Years:**

Chairperson Conroy stated that at the July 2005 Board Meeting, the board identified those pharmacists with 50 years of licensure as a pharmacist and publicly commended them.

The pharmacists so honored receive a letter from the board's president and a commendation. Each is invited to a future board meeting to be publicly recognized. Additionally, his or her name is published in *The Script.*

Since July 2005, the board has acknowledged 516 pharmacists:

July 2005:	450	pharmacists
Oct. 2005:	50	pharmacists
Jan. 2006:	8	pharmacists
Apr. 2006:	8	pharmacists

Chairperson Conroy stated that recognition of the pharmacists with 50 years of service who attend this board meeting will occur during the break at this meeting.

- **Recognition of Those Who Provided Disaster Response to Victims of the Gulf Coast Storms:**

Chairperson Conroy stated that following the October 2005 Board Meeting, the board created a special location on its Web page to highlight the activities of those pharmacists who provided relief to Gulf Coast storm victims. This feature was highlighted in the October 2005 *The Script.*

At the January Board Meeting, the board played a video montage set to music prepared from photos taken principally at the New Orleans Airport by California Pharmacist Michael Sohmer.

Until mid-March, the board received no other information about pharmacists' activities providing relief to Gulf Coast storm victims. In March, the board received a list by county of pharmacists who provided relief as part of DMAT teams.

Chairperson Conroy stated that each of the individuals on this list received a commendation and personal thank you from Board President Goldenberg.

Each of these individuals has been invited to a future board meeting, where each can be publicly commended. Recognition of those pharmacists who are able to attend this board meeting will be will occur during the break.

Chairperson Conroy reported that at the National Association of Boards of Pharmacy National Meeting in April, Executive Officer Harris moderated a segment on Structuring an Effective Disaster Plan. Pharmacy responses to the Gulf Coast Storms from a number of states, primarily Mississippi and Louisiana were the focus of this presentation. Additionally, Dr. Sohmer's video montage of the early days of Katrina relief at the New Orleans Airport, which he had shortened from the version shown at the February Board Meeting, was shown to an appreciative NABP audience.

The board again thanked Dr. Sohmer for his DMAT efforts and his video that displayed photos of New Orleans relief.

- **2006 - 2011 Strategic Plan Revision**

Chairperson Conroy invited the public to attend the strategic planning meeting on April 27.

The board truly manages its operations by its strategic plan. The current structure, objectives, and reporting mechanisms seem up to date. However, other sections, dealing with internal and external factors that influence the board may need revision. A half day will be devoted to this.

- **Relocation of the Department of Consumer Affairs and Board of Pharmacy:**

Chairperson Conroy stated that the board moved into its new office the weekend of December 9 as scheduled.

The board is still working with the department to secure modifications to the phone system. The new computer-based telephone system is not functioning optimally for the board's callers, and will have to be reprogrammed. One problem is that the new system relies upon individual phone numbers, and not extension numbers as the board used in its former location. Obtaining the individual phone numbers of the desired staff person requires the caller to listen to a lengthy phone tree message – the system does not allow the entering of a "0" to reach a live operator until the very end of the phone tree message.

Once the department is ready to aid the board in modifying the system, board managers will revamp the system to improve service.

- **NABP National Meeting in San Francisco in April 2006, and Districts VII and VIII Meeting in Anaheim in October 2006:**

Chairperson Conroy stated that this year, two of the National Association of Boards of Pharmacy major meetings will occur in California:

- California April 2006: The NABP annual meeting took place in San Francisco.
- October 2006: The NABP Districts VII and VIII meeting will be in Anaheim.

At the NABP April Annual Meeting, the board staffed the "Hospitality Suite" on April 8 and 9. The board also participated in a poster session involving the new "Notice to Consumers" poster. Board President Goldenberg opened the first business session on April 9 with "words of welcome."
Executive Officer Harris moderated a discussion section on April 11 involving disaster response to the Gulf Coast storms by pharmacists and pharmacies.

- **Proposed Meeting Dates for 2007**

Chairperson Conroy stated that proposed meeting dates for the rest of 2006 and 2007 are:

2006

- July 19 and 20 – San Diego
- October 25 and 26 – San Francisco/Bay Area *(CSHP's Seminar is in Sacramento on Oct. 12-15)*

2007

- January 31 and February 1 -- Orange County/Los Angeles *(CPhA's Outlook is February 15-18 in Palm Springs)*
- April 18 and 19 – Sacramento *(NABP's Annual Meeting is in Portland, Oregon in May)*
- July 25 and 26 – San Diego

- October 24 and 25 -- San Francisco/Bay Area *(CSHP's Seminar is October 18-21 in Palm Springs)*

- **Sunset Review:**

The board was scheduled to undergo "sunset review" by the Legislature this fall. During a sunset review, all aspects of the board's consumer protection activities are analyzed in detail by a subcommittee of the Legislature. The goal is to eliminate unnecessary licensing agencies, and assure that all DCA boards and bureaus are effectively providing efficient and valuable consumer protection. If the Legislature deems that a board is not worthwhile, it "sunsets" or folds into the Department of Consumer Affairs, and the board is dissolved.

Due to a number of factors (including that this is election year, the end of the senate term of Chairperson Liz Figueroa, who was a key advocate for sunset review, and a large number of agencies set for review this year), the board's sunset date will be delayed two years – until 2008. Legislation will be introduced to contain this delayed date.

- **Budget Update and Report**

I. Budget Report for 2005/06

The current fiscal year ends June 30, 2006. This fiscal year the board received repayment of $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund. This repayment is classified as revenue for the year. Three million dollars is still owed to the board from the 2001 loan.

- ***Revenue Projected: $9,010,133***

The board's revenue for the year is projected to be comprised of:

Licensing Fees (estimated):	$5,360,000
Interest	$90,000
General Fund Loan repayment	$3,227,000
Cite & Fine (actual as of 3/31/06)	$202, 408
Cost Recovery (actual as of 3/31/06)	$130,725
	$9,010,133

- ***Expenditures Projected: $7,954,121***

The board's maximum expenditure authority for the year is $7.9 million.

II. Governor's Proposed Budget for 2006/07

Ms. Herold stated that the Governor's proposed budget for the next fiscal year starting July 1, 2006, was provided to the Legislature in mid-January. In late March, the Senate and Assembly

budget subcommittees began their review of the budget. There are currently no issues with the board's budget.

Over the next few months, the Legislature will hold hearings and likely modify the proposed state budget. The Legislature is required to complete its review and pass a budget bill by June 15, 2006. The Governor may then deduct items from the budget enacted by the Legislature (called a "blue pencil veto") but cannot add money to any budget item.

- ***Revenue Projected: $5,356,000***

  Revenue for the next fiscal year is projected to be comprised of $5,316,000 in fees and $40,000 in interest on money in the board's contingency fund.

- ***Expenditures Projected: $8,446,000***

  Expenditures for next year are $240,000 more than those projected for this fiscal year; this increase includes:

  -- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000s. ($208,000)

  -- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)

  Note: Funding to program areas have increased or decreased; the net effect is a budget of $240,000 more than this year.

  The board will receive restoration of one inspector position, one receptionist position and one half-time public outreach position.

III. Board Fund Condition

The board's fund condition is a snapshot of its "solvency," in this case meaning whether the revenue collected is sufficient to sustain expenditures. Over the last few years, the board's annual expenditures typically have exceeded its annual collected revenue. Normally this would be a huge problem that would trigger budget cutbacks or fee increases, but the board has had a surplus of money in its fund (which can be thought of as the board's savings account). The board has been trying to spend down this surplus for several years, eliminating a surplus condition caused by the 1999 repayment of a loan to the state's General Fund (during another budget crisis in the early 1990s).

The board must watch its fund condition, however, because if it gets low or into a deficit, the board will run out of money for annual operations (since expenditures exceed revenue collected). The Business and Professions Code provides that the board should maintain a reserve of 12 months of annual expenditures as a prudent reserve. However, state budget officials do not agree

that this much money needs to be kept as the board's reserve. They prefer a reserve of 3-6 months.

The board ended the last fiscal year (on June 30, 2005) with a reserve of $4,111,000. This is 6.2 months of expenditures.

The board's fund condition projections on June 30 over the next few years (as estimated in early January 2006) are:

- 2005-06: The reserve is estimated at 7.1 months (after repayment of the $3 million).
- 2006-07: A reserve of 2.9 months is projected.
- 2007-08: A reserve of 2.1 months is projected (includes planned repayment of $2.5 million borrowed in 2001).
- 2008-09: A deficit in the reserve of is projected of –1.7 months (includes the last repayment of $500,000 borrowed in 2001)

A fee increase will be needed to take effect July 1, 2008 to prevent a deficit during 2008-09. Board staff will continue to watch these figures closely.

IV. Board Member Expenditures and Reimbursements

Dr. Conroy stated that the travel expenses and compensation of board members claimed this fiscal year was provided in the board packet.

- **Update on I-Licensing Project – Online License Application and Renewal:**

Approximately seven DCA agencies have the ability to provide online license renewal due to participation in a project started under the Davis Administration. However, the state's budget crisis in the early 2000s prevented the Board of Pharmacy from joining this project, although the board has been striving to be added for years.

Ms. Harris stated that the DCA is now moving ahead with a proposal so other agencies can offer online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future.

However, at the direction of the Department of Finance, all work on the project has been stopped until the next fiscal year (July 1). A budget change proposal will need to be written and approved for the board to participate in this project in the future as well. The DCA will be developing this budget change proposal for all participating agencies.

No costs are yet available for this conversion, and it will be approximately two years before implementation at the board.

- **Personnel Update and Report**

Ms. Herold stated that there have been a number of personnel changes at the board in the last three months.

First, Rosario Navarro, a board cashier, died in March after a long illness. Ms. Navarro worked for the board for six months before becoming ill. Staff has sent condolences and heart-felt sympathy to Ms. Navarro's family.

Supervising Inspector Dennis Ming has announced his plans to retire on July 1. Dr. Ming has been with the board for six years – three years as an inspector and three years as a supervising inspector. Dr. Ming was instrumental in establishing the sterile compounding pharmacy licensure program and is a supervisor of the compliance team. Dr. Ming will remain on the board's staff as a retired annuitant. Dr. Ming brought strength to the board from his years as an educator and a pharmacist. Dr. Conroy commended Dr. Ming for his work on the sterile compounding pharmacy licensure program.

Inspector Nahal Bahrampour resigned at the end of February. Dr. Bahrampour worked for the board for about five years. This leaves the board with one inspector vacancy.

The board will also gain one inspector position July 1 with the new state budget.

Consequently, the board is now seeking the department's support in scheduling two civil service examinations from which pharmacists can be hired to work for the board as inspectors and as a supervising inspector. This process will take at least four, and possibly six months.

Other staff changes:

- Legislative Coordinator Jan Perez is ending her training and development assignment with the board at the end of April, and will return to the Department of Fish and Game.
- Licensing Unit Manager Anne Sodergren will become the board's new legislative coordinator.
- Associate Analyst Sue Durst has been transitioned into the board's computer support position. She will continue to be the board's CURES analyst as well.
- Analyst Kim DeLong has become the board's Web site coordinator. She is currently working on restructuring the board's Web site, and will continue to work on mail votes.
- Technician Judi Collins has been transitioned into the board's enforcement unit to work on disciplinary background checks of applicants and licensees.
- Veronica Hagen will become the board's renewal cashier. Ms Hagen is currently a part-time receptionist, and began work for the board six months ago.
- Technician Eleonor Steiner will become the licensing technician for wholesalers and designated representatives.
- The board has hired Analyst Victor Perez from the Department of Health Services. Mr. Perez will work in the enforcement unit and we will use his graphic arts skills for all our

publications, newsletters and forms.

Board Member Positions:
The board itself has two public board member positions and one professional member position vacant.

Additionally, John Jones is completing the year of grace on his second term. He will end his tenure on the board on June 1. Dave Fong and Richard Benson are both completing their year of grace on their first terms. Both are eligible for reappointment, but unless reappointed, cannot serve on June 1. This leaves the board with exactly a quorum of seven members on the board.

- **Approval of Full Board Minutes (February 1 and 2, 2006)**

President Goldenberg asked if there were any corrections to the minutes of February 1 and 2, 2006.

MOTION: Approve the board minutes of February 1 and 2, 2006.

M/S/C: POWERS/SCHELL

SUPPORT: 9 OPPOSE: 0

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zinder reported on the public meeting of the Communication and Public Education Committee meeting held in Sacramento on April 4, 2006.

There were three pharmacists who attended this meeting who requested 2 hours of CE credit in accordance with the board's new policy.

- **Update on the Development of Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care**

Chairperson Zinder reported that two years ago the board approved a proposal to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet series by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care.

At the April 2006 meeting, the committee reviewed nine fact sheets that are now being distributed. The fact sheets contain general information on the topic, and contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

These fact sheets are:

General Pharmaceutical Care Issues

1. "Is Your Medicine in the News?"
2. "Generic Drugs . . . Real Medicines at High Quality, Low Cost"
3. "Lower Your Drug Costs So You Can Keep On Taking Your Medicines"
4. "Don't Flush Your Medicines Down the Toilet"

Medicine Safety

5. "What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!"
6. "Ever Miss a Dose of Your Medicine? Here Are Some Tips"
7. "Thinking of Herbals? Check Carefully Before You Take Them with Medicines"

Health Topics

8. "Diabetes – Engage Your Health Team"
9. "Did You Know? Good Oral Health Means Good Overall Health"

The fact sheets will be distributed at consumer outreach fairs and will be listed on the board's Web site. The board will also announce their availability in the next *The Script* and via a subscriber alert.

The Center for Consumer Self Care is working with other students to develop additional fact sheets.

- **Update on Activities of the California Health Communication Partnership**

Chairperson Zinder reported that last year, the board voted to become a founding member of the California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion. The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

At the April Communication and Public Education Meeting, Bill Soller, PhD, of the Center for Consumer Self Care, made a presentation about the recent activities of the partnership.

Past campaigns are:
2004-05: Preserve the Treasure – avoiding antibiotic overuse
2005: Generic Medicines – same as brand names at lower costs
2005: It's Your Life – breast cancer and prostate cancer screening.

The third project aired in September and October 2005, and was funded by a grant from a private foundation, which enabled use of a firm (the North American Precis Syndicate) that specializes in dissemination of public service announcements and prewritten articles to a diversity of media outlets nationwide. The board used the same firm for similar dissemination services in the late 1990s.

This cancer screening campaign was among the most successful campaigns ever released by this distribution firm in terms of the number of messages published and aired.

Proposed for future campaigns are:
2006: It's Your Life – breast and prostate cancer screening awareness
2006: Generic Medicine
2006: Diabetes and Aspirin

During the April meeting, the committee discussed the importance of public education campaigns about pharmacist-to-patient consultation since many consumers are not aware of this requirement and the importance of seeking and following a pharmacist's knowledge of drug therapy and how this can benefit their health. The committee also suggested that some form of outreach to educate other health care providers about a pharmacist's requirement to consult would benefit both providers and patients.

The committee thinks this is an important area for strategic planning discussions at the April Board Meeting.

- **Request for Joint Public Outreach with the Department of Health Services, Office of AIDS to Increase Awareness of Access to Syringes in Pharmacies without a Prescription**

Chairperson Zinder stated that at the October 2005 Board Meeting, the board agreed to collaborate in an informational campaign with the DHS Office of AIDS, aimed at educating pharmacists and the public about the provisions of a new law that allows local health jurisdictions to authorize nonprescription syringe sales by pharmacies to prevent HIV and Hepatitis (Senate Bill 1159, Vasconcellos, Chapter 608, Statutes of 2004).

Tom Stopka, a research scientist with the Office of AIDS attended the board meeting and provided information about this program to the board. Dr. Stopka provided information on SB 1159 and the disease prevention demonstration projects that are taking place across the state, and expressed interest in working with the board and opportunities to further collaborate.

Dr. Stopka stated that 19 percent of cumulative AIDS cases in California are attributed to injection drug use. Over 1,000 injection-related HIV infections occur each year in California. In terms of Hepatitis, as of 2001, approximately 6,000 HCV have occurred in California. He reported that approximately 60 percent of HCV cases are attributed to addiction drug use and 5,000 new HCV infections occur annually.

Dr. Stopka stated that SB 1159 was signed by Governor Schwarzenegger and became effective in January 2005. SB 1159 allows local health jurisdictions to establish a disease prevention demonstration project, eliminates the requirement for pharmacists to keep a log of syringe sales and decriminalizes possession of 10 or fewer syringes obtained from authorized sources. The law will expire in 2010.

Dr. Stopka stated that the average lifetime cost for treating a person with AIDS is approximately $195,000 and treatment of chronic liver disease related to HCV is approximately $20,000 per person per year. He added that by reducing the number of injection drug use-related HIV/AIDS and HCV cases can reduce the economic burden on county funded care and treatment programs.

Dr. Stopka stated that participating pharmacies are required to register within their county, store syringes behind the counter and provide for disposal of the syringes through on-site syringe disposal programs or furnishing or selling mail-back sharps containers, or furnishing or selling personal sharps containers.

The board published one article in a recent *The Script* to educate pharmacists, and distributed information about the program from a board information booth held at CPhA's annual meeting in February. A copy of a draft brochure, developed by the Office of AIDS will be promoted in a future issue of *The Script.*

The board supported the committee's suggestion for staff from the Office of AIDS to develop an article about how the program has been implemented in a pharmacy in California, for publication in the board's newsletter.

- **Update on *The Script***

Chairperson Zinder stated that the next issue of the board's newsletter is being developed for publication in July 2006.

In response to comments made by the committee and at the February Board Meeting, the newsletter will resume listing disciplinary actions taken. The name of the licensee will be listed along with the disciplinary action.

In a future newsletter, the board will publish statistics on the top 10 corrections ordered during inspections and the types of fines the board has issued under the citation and fine program.

Chairperson Zinder acknowledged the Pharmacy Foundation of California who has recently found a sponsor to fund the printing and mailing to California pharmacists of the January 06 issue of *The Script.*

- **Mailing to Pharmacies of Revised "Notice to Consumers"**

Chairperson Zinder stated that the California Code of Regulations Section 1707.2 requires that pharmacies display a specifically worded "Notice to Consumers" poster that among other items, contains five questions that patients should understand about taking their medications. This poster has been required to be posted in pharmacies since 2002, and are important to

encourage patients' improved understanding about their drug regimens and foster a dialogue between patients and pharmacists.

Because of the board's new business address and telephone number, the board recently updated the poster to reflect this new information. The board is now mailing these new posters to the state's 6,000 community pharmacies, along with a letter from Board President Goldenberg emphasizing the importance of pharmacist to patient consultation and the requirement to display this poster.

The poster is 17 x 22 inches and has been translated into Spanish, Chinese, Vietnamese, Russian and Korean.

- **Pharmacy Law Online and in Published Lawbooks**

Chairperson Zinder stated that pharmacy law is detailed and complicated and the board strongly encourages licensees to seek out answers to their legal questions by accessing pharmacy law. To make this easier, there are several ways individuals can access the provisions of pharmacy law.

1. The board has on its Web site a copy of all pharmacy laws and regulations. The address is http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

   There are several advantages of using this source for Pharmacy Law. It is free. It also contains a detailed index, developed and used by board staff, that is not published in either lawbooks listed below.

2. LawTech publishes a lawbook, and also has a cd version available for sale. Ordering information is available via a link from the board's Web site or by calling 1-800-498-0911 X 5.

   The cost for this Lawbook is $21.99.

   LawTech has published the board's lawbook for the last six years.

3. Lexis/Nexis has also produced its first version of the board's lawbook with a cd version of this publisher's lawbook available.

   This lawbook is available for $22, by calling 1-800-833-9844.

The board will promote this information in its next newsletter.

Chairperson Zinder continued that the board regrets that it lacks the staff to provide answers to all inquiries the board receives involving interpretations of pharmacy law. Discussions

with board inspectors during routine inspections and the self-assessment forms are two additional ways licensees can use to find answers to many of their questions.

The board advises licensees to contact their legal counsels for legal advice. Individuals may also submit questions in writing to the board; however, the board cannot personally answer all questions it receives. In the future, some of these questions and answers will be placed in the newsletter so they can be shared with all licensees.

- **New Consumer Brochures**

  Chairperson Zinder stated that board staff has developed four new consumer brochures and fact sheets.
  - "Medicare Part D – Selecting a Prescription Drug Plan"
  - "Children and Their Medicines"
  - "Do You Sometimes Forget to Take Your Medicines"
  - "New Easier to Read Prescription Drug Information"

  Under development are:
  - The Beers list of medications that should not be provided to elderly patients
  - Update of Facts About Older Adults and Medicines (revision)

- **Center for Health Improvement Report: "Opportunities for Improving the California Pharmacist-Patient Consultation Process"**

  Chairperson Zinder stated that the board was a cosponsor of a recent survey on the mandated pharmacist to the patient consultation process and its effects on Californians aged 65 and over. A final copy of the report was recently printed and released.

- **Update on Public Outreach Activities**

  Chairperson Zinder stated that the board strives to provide information to licensees and the public. It develops and distributes consumer materials at health fairs and attends as many of these events as possible, where attendance will be large and staff is available.

  The board also has a Power Point presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, and is well received by the individuals present.

  Also in the spring, the board makes presentations on pharmacy law and on applying for the California pharmacist licensure examination to students in California's pharmacy schools.

Since the February 2006 report to the board, the board has made four presentations to licensees or law enforcement associations, attended two public health fairs and made presentations to students at four California schools of pharmacy.

Also noteworthy is that Board President Goldenberg provided welcoming remarks to the opening session of the National Association of Boards of Pharmacy Annual Meeting in San Francisco. Other board presentations at this annual meeting included moderation of a panel discussion by Executive Officer Harris on emergency preparedness including a video montage specifically prepared by Michael Sohmer, Pharm.D. for this event.

BOARD OF PHARMACY RECOGNITION

- **Richard Benson, Board Member**

President Goldenberg recognized Richard Benson and announced that this would be his last board meeting as he was completing his term on the board. President Goldenberg stated that Mr. Benson would be invited to attend a future meeting so the board can formally acknowledge his service on the board. President Goldenberg added that Mr. Benson has served as president of the United Food and Commercial Workers since 1994 and has served the union as counsel. He was appointed by Chief Justice Ronald George to the Task Force of the Quality of Justice and also served on the subcommittee of Alternative Dispute Resolutions and the Judicial System. Mr. Benson earned his Bachelor of Arts Degree at Golden Gate University and while serving on the board, has been a member of the Communication and Public Education Committee and Licensing Committee. President Goldenberg stated that Mr. Benson has brought to the board a perspective in both the pharmacy aspect and labor aspect of the practice of pharmacy.

Mr. Benson thanked the board.

- **John Jones, Board Member**

President Goldenberg recognized John Jones for his hard work dedication and leadership while serving on the board. Mr. Jones set an example for all board members in decision-making based on evidence. He added that Mr. Jones' presence would be felt on this board for many years to come. President Goldenberg presented Mr. Jones with an inscribed clock.

Mr. Jones stated that for some time he dreaded this day when it's time to say goodbye. Mr. Jones stated that serving on the board has provided him with one of the most rewarding experiences of his professional life; one that has truly shaped his identity. He added that he will miss everyone very much and he commended board members and staff on their exemplary actions. He thanked the board for the opportunity to serve.

- **Dennis Ming, Supervising Inspector**

President Goldenberg announced Dr. Ming's retirement from the Board of Pharmacy beginning in July. President Goldenberg stated that Dr. Ming has served the board in an exemplary fashion and has contributed greatly in making California a better place for all consumers. He added that we can all learn from his dedication, knowledge and commitment to excellence. Dr. Ming will continue working part time with the board as a retired annuitant.

Dr. Ming thanked the board, Ms. Harris and Ms. Herold, Supervising Inspectors Bob Ratcliff, Judi Nurse and Joan Coyne. He added that he found that his job with the board was the most professionally enjoyable of his careers; mainly because of the opportunity it provided him to make an impact on the pharmacy profession.

- **Recognition Program for Pharmacists Who Have Been Licensed for 50 Years**

  - **Karl Hanke**

    Mr. Hanke attended the meeting and was recognized by the board for 50 years of licensure as a pharmacist. Mr. Hanke recognized his daughter Lisa Shelley who was in the audience and he stated that she graduated from the UOP Pharmacy School.

  - **Martha Gray Mason**

    The board recognized Ms. Mason for 50 years of licensure as a pharmacy. Ms. Mason stated that among all of the good and bad decisions made in her life, the decision to become a pharmacist was the best decision she has made.

President Goldenberg stated that recognizing pharmacists who have 50 years of service has been one of the most rewarding systems that the board has developed.

President Goldenberg encouraged community participation during disasters and stated that significant disaster response has to start at the community level. He added that the board will make this a part of its strategic planning session. He stated that each individual in the community can do his or her part to assist in a positive fashion during the occurrence of a disaster, since government may not be able to provide much support initially.

- **Report of the Subcommittee Meeting on Medicare Drug Benefit Plans on April 4, 2006**

President Goldenberg noted that minutes from the boards Subcommittee on Medicare Drug Benefit Plans Meeting of April 4, 2006 have been prepared and are in the board packet materials. Representatives from the Centers for Medicare and Medicaid Services, patients, patient advocates and pharmacists attended this meeting.

LICENSING COMMITTEE

- **Report on the Meeting of March 22, 2006**

Chairperson Conroy reported on the Licensing Committee Meeting on March 22, 2006.

- **Request to Modify Intern Hours Earned for Pharmacy-Related Experience Outside a Pharmacy (16 CCR § 1728).**

Chairperson Conroy announced that the Board of Pharmacy has postponed the decision on this issue until the next board meeting but will be taking comments. She added that the committee did bring this before the full board without a recommendation.

Chairperson Conroy stated that pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its regulations to allow up to 1,000 of 1,500 hours of intern experience required to take the pharmacist license exam to be earned for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. Under current regulation, the board has the discretion to grant a maximum of 600 hours for experience substantially related to the practice of pharmacy and an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. California pharmacy students earn the 600 non-pharmacy hours for school-required experiential training (clinical clerkship).

Therefore, if adopted as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

It was noted that opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth year in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. It was anticipated that a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The National Oncology Alliance, Inc. (NOA) spoke in support of the proposal and gave a presentation on opportunities that it has for interns outside a licensed pharmacy and under the supervision of a pharmacist. The intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as it applies to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria and content outline of the California Pharmacy Jurisprudence Examination (CPJE).

Dean Koda-Kimble from the UCSF, School of Pharmacy submitted a letter expressing concern over the proposal and urged the board not to amend the regulation.

At the committee meeting, the committee discussed the board's responsibility to protect the public and felt that it is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

Four students from UOP and UCSD presented their remarks to the board, requesting more flexibility with earning intern hours.

Students at UCSD are conducting a survey that will be distributed to students, practitioners, and a random sampling of the people of California to determine out who is interested in this change.

The students explained how the 20-question survey would target practitioners and the industry such as potential employers to determine if people want this, is there support from students, practitioners and employers in California. It was anticipated that the study would be completed by June.

All seven schools of pharmacy agree that this effort would better the pharmacy profession.

President Goldenberg stated he is proud of the students for stepping forward on this issue and added that this item should remain on the board's agenda and if the report has not been completed by July, the students could provide an update at the board meeting on how the study is progressing.

Mr. Powers stated that he reviewed the material on this issue and he felt that the committee had concerns about how this would impact the number of intern hours of experience were earned in community and hospital pharmacy rotations. There was concern that students would graduate without being well rounded in the mechanics of prescription filling. He added that even if students do not choose as their profession the conventional practice of pharmacy, it is cited as a requirement that students understand the mechanics of the practice.

President Goldenberg suggested that the students also direct the survey to consumers.

Ms. Zinder questioned if students could perform their required 1500 hours in addition to seeking the alternative internships. The response was that student's schedules are too strict.

John Cronin referred to a letter dated April 18, from Dr. Koda-Kimble, Professor and Dean, UCSF, that states that the current regulation provides ample opportunity for students to pursue innovative experiences without jeopardizing their ability to complete the board's requirements before graduation. In the letter, Dr. Koda-Kimble requests that the board adopt a statement of competencies to be gained from internship experiences in licensed pharmacies to be used to guide both students and preceptors in creating experiences that develop core competencies and skills the public deserves. Mr. Cronin added that with a core list of competencies, you would know if 500 hours were enough and this should be the focus.

- **Request to Re-approve the Accreditation Commission for Health Care, Inc. (ACHC) and Community Health Accreditation Program (CHAP) as Accreditation Agencies for Pharmacies that compound Injectable Sterile Drug Products.**

  Chairperson Conroy stated that B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

  The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for three years. At that time, ACHC accredited both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. Recently ACHC has been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare.

  In July 2003, the board approved Community Health Care Accreditation Program (CHAP) as an accreditation agency. CHAPS is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. Currently, one California pharmacy is CHAP accredited and two pharmacies have applied. There are 63 CHAP accredited pharmacies in 23 states and 16 pharmacies that have applied for accreditation.

  Supervising Inspector Dennis Ming reported that the board has not found any compliance issues with either ACHC or CHAP accredited pharmacies

  In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

1. Periodic inspection – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payors – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

MOTION: Licensing Committee: That the Board of Pharmacy re-approve the Accreditation Commission for Health Care, Inc. (ACHC) and Community Health Accreditation Program (CHAP) as accreditation agencies for pharmacies that compound injectable sterile drug products.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Adopt a Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products.**

Chairperson Conroy stated that Business and Professions Code section 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved the Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for three years. In July 2003, the board also approved Community Health Care Accreditation Program (CHAP) as an accreditation agency.

Since both agencies have requested that the Board of Pharmacy approve them again as accreditation agencies, and if the approval is granted, it is being recommended that the board pursue a regulation to recognize these agencies in regulation as the Joint Commission on the Accreditation of Healthcare Organizations is recognized in statute.

In addition the regulation would include the application and approval process, the evaluation factors, require the board's self-assessment form for sterile injectable compounding pharmacies as part of the survey process, and that a copy of the survey report be submitted to the board. If the board agrees with this recommendation, proposed language will be drafted.

MOTION: Licensing Committee: That the Board of Pharmacy re-approve the Accreditation Agencies for Pharmacies that compound sterile injectable drug products.

SUPPORT: 9 OPPOSE: 0

- **Request to Extend the Waiver for the Study by UCSF School of Pharmacy and Cedars-Sinai Medical Center to Allow a Technician to Check a Technician in the Filling of a Unit-Dose Medication System in a Hospital Inpatient Pharmacy**

Chairperson Conroy stated that Peter Ambrose, Professor of Clinical Pharmacy at UCSF and Rita Shane, Director of Pharmacy Services for Cedars-Sinai Medical Center requested an extension of the waiver for the study by UCSF's School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting." In April 2004, the Board of Pharmacy granted a two-year waiver for this study. After board approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Center and the Committee on Human Research at UCSF. In order to complete the data collection, analysis and review the results, an extension until December 31, 2006 has been requested.

This study was a sequel to the experimental program that evaluated pharmacy technicians checking other pharmacy technicians in a unit-dose drug distribution system in a hospital pharmacy.

The purpose of the sequel study is to evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional patient-care functions. The special expertise of pharmacists in the management of drug therapy benefits patients.

Preliminary data from the study was provided to the board at its July 2005 meeting and a summary of results from June 21, 2004 – January 1, 2006, was included in the board packet.

At the February meeting, the board approved for hearing a proposed a regulation change to allow a specialized trained pharmacy technician to check another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy that has a clinical program. This hearing is set for this board meeting. If the board approves the proposed regulation, it will take approximately 6-9 months before the regulation would become effective.

Dr. Ambrose provided the board with an update to the study and the results to date. Dr. Ambrose stated that the study found that inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians. The current study is reviewing the impact of having pharmacists prevent medication errors that are associated with both the prescribing staff and the administration staff in acute care settings using unit dose medications to demonstrate what pharmacists are doing with their time. Approximately 1 hour and 15 minutes per pharmacist per day is redeploying into the clinical environment so instead of checking cassettes, pharmacists were in the patient care wards and interacting with physicians and nurses.

He stated that the results to date continue to demonstrate the positive impact on patient care and medication safety that can be achieved by creating time for pharmacists to interact with the nursing and medical staff rather than using pharmacists to perform the non-discretionary task of checking technician-filled unit-dose medication charts. Also, it was demonstrated and published in a peer-reviewed pharmacy how specially trained technicians can very accurately stock and check unit-dose medication carts while still incorporating a quality assurance system. It is the use of pharmacy technicians in this capacity that creates the time for pharmacists to utilize their clinical skills to assist physicians and nurses to reduce medication errors at the prescribing and administration steps. Dr. Ambrose's report can be downloaded from the board's Web site at www.pharmacy.ca.gov under the materials for the April 2006 Board Meeting, within the Licensing Committee section.

During the 80 weeks of the study so far:

- Pharmacists prevented 1,241 potential prescribing errors
- Pharmacists prevented 614 potential administration orders
- The leading types of errors intercepted were:
    - Omission errors 20.6%
    - Improper dose/quantity 25.6 %
    - Unauthorized drug 2.1 %
    - Extra dose 3.7 %
    - Wrong patient 4.1 %

- Pharmacists prevented 682 medication errors with potential harm – of which
    - 590 encounters prevented temporary harm
    - 28 encounters prevented permanent harm
    - 60 encounters prevented an increase in hospital stay
    - 4 prevented death

Dr. Ambrose stated that one aspect of the study is to develop a CQI process to see where problems are occurring, which drugs are most problematic, and whether there are certain prescribers that are problematic. This offers a chance to see where the problem is and change the system to avoid errors.

Dr. Rita Shane, representing Cedars-Sinai, stated that the study demonstrates the value of pharmacists. There have been a number of occasions when the pharmacist identified wrong orders because the pharmacist was aware of the patient's diagnosis and reviewed the patient's entire medication regimen.

Steve Gray, representing Kaiser Permanente, stated that he supports the study by Cedars-Sinai and UCSF School of Pharmacy because it will be very valuable to other organizations.

MOTION: Licensing Committee: That the Board of Pharmacy extend the waiver to December 31, 2006 to allow a technician to check a technician in the filling of a unit-dose medication system in a hospital inpatient pharmacy for the study "Evaluation of the Impact on Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting" by UCSF School of Pharmacy and Cedars-Sinai Medical Center.

SUPPORT: 9 OPPOSE: 0

- **National Association of Boards of Pharmacy Announcement Regarding the Evaluation Process for Foreign Pharmacy Graduates**

Ms. Harris stated that the National Association of Boards of Pharmacy (NABP) announced its partnership with the Educational Credential Evaluators, Inc. (ECE) for the educational credential evaluation of applicants to the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program. This partnership will change the method by which foreign pharmacy graduates will be evaluated.

ECE will be responsible for verifying the educational background of the applicant and the NABP will verify the applicant's professional licensing and registration information. The foreign graduate will submit all documents directly to ECE for evaluation.

This new partnership is intended to address the increase of workload that this program has experienced over the last few years and reduce the processing time for these applicants.

California requires all foreign graduates to be FPGEC certified before they can apply to be licensed as an intern or pharmacist.

- **Changes to the Pharmacy School Accreditation Procedures by the Accreditation Council for Pharmacy Education (ACPE)**

Chairperson Conroy stated that ACPE recently announced changes to its accreditation procedures. After June 30, 2006, ACPE will require that any new doctor of pharmacy program seeking preaccreditation status must progress through both states of preaccreditation, which is precandidate and candidate phases, before consideration of full accreditation. Prior to this policy change, it was not essential that a program be granted precandidate status before students were admitted.

After June 23, 2006, a new program must achieve precandidate status before admitting students. Should a new program admit students without achieving precandidate status, this will preclude ACPE from considering the program's application for candidate preaccreditation status, and full accreditation cannot be considered until graduation of the first class. Students graduating from a program without candidate status will thus have graduated from a program with no accreditation status and will likely not be eligible for licensure.

This change in policy is consistent with the board's recent regulation change that states that the board will recognize a school of pharmacy that is accredited or granted candidate status by ACPE or schools recognized by the board. The board has recently "recognized" new schools of pharmacy that have been granted precandidate status so that the students can be registered as interns.

- **Report on ACPE Site Visits**

Chairperson Conroy stated that it was reported that board members have been actively participating on the ACPE evaluation teams for the California schools of pharmacy. President Goldenberg participated in the recent evaluation of Western University of Health Sciences College of Pharmacy. Former board member Darlene Fujimoto was on the team that evaluated UC San Diego Skaggs School of Pharmacy. The evaluation conflicted with the board's February meeting so Dr. Fujimoto graciously agreed to be the board's representative. Board member Ruth Conroy will be on the site team for Loma Linda University School of Pharmacy scheduled for April 18th – 20th. ACPE was scheduled to evaluate the Touro University California College of Pharmacy for candidate status on April 25-27, 2006, and former board member John Tilley agreed to represent the Board of Pharmacy because it conflicted with the board meeting.

- **Competency Committee Report**

Ms. Herold referred to the supplemental statistics for the CPJE for the last six months that ended April 1, 2006. The pass rate for the CPJE is 80.3 percent; the pass rate for California graduation is 89 percent. These statistics can be found at www.pharmacy.ca.gov.

Ms. Herold stated that the board posted the new content outline on the board's Web site and this was also included in the January 2006 newsletter. All exams administered since April 1, 2006 use this structure.

The California Pharmacy Jurisprudence Examination (CPJE) handbook is in the process of being updated and will include the new content outline. There is also a sample CPJE exam that is posted on the board's Web site.

The Office of Examination Resources (OER) within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. The winning vender will be announced on May 8, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

ENFORCEMENT COMMITTEE

- **Report on the Meeting of the Workgroup on E-Pedigree of March 16, 2006**

  Chairperson Powers reported on the meeting of the Workgroup on E-Pedigree of March 16, 2006.

- **That the Board of Pharmacy Consider the Requests to Delay Implementation of the Electronic Pedigree until January 1, 2008.**

  Mr. Powers noted there was a detailed summary of the March 16, 2006 workgroup meeting contained in the board packet.

  In 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

  Over the last year, the Enforcement Committee has been monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. At the February board meeting, the board agreed to form a Workgroup on E-Pedigree, which held its first meeting on March 16, 2006 and was attended by over 60 stakeholders.

  At this first workgroup meeting, there were several presentations. Supervising Inspector Judi Nurse presented on California's requirements for electronic pedigree. Mike Rose from Johnson and Johnson and Ron Bone from McKesson as Co-Chairs of the EPCglobal Healthcare and Life Sciences Business and Action Group presented on the state of electronic pedigree and Radio Frequency Identification (RFID) technology standards. Walt Slijepcevich of Pfizer presented on Pfizer's Viagra RFID authentication pilot program and Bob Dufour from Wal-Mart Stores gave an overview of its experience with RFID.

To address questions regarding the implementation of the e-pedigree requirement, a question and answer document was prepared.

Of greatest concern to the many that attended this March workgroup meeting was the implementation date of January 1, 2007. Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

The board has received requests for delay in implementation. At the September 2005 Enforcement Committee meeting, Amgen stated that it will be extremely difficult to meet the January 1, 2007 deadline.

In addition, the board has received letters from the Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), Biogen Idec seeking a delay in implementation to January 1, 2008, because of concerns that it is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies to implement and comply with the requirements of an electronic pedigree.

It was expressed that 12 states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

However, the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is inimical to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Alternatively to provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

The delay on the effective date of the pedigree provisions in the federal Prescription Drug Marketing Act (PDMA) expires December 2006. In February 2006, the federal Food and Drug Administration (FDA) held a Counterfeit Drug Task Force Public Workshop to receive comments. It was reported that the Task Force plans to issue its final report to the Commissioner in May. The FDA was requested to create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states.

The board has received two more letters requesting a delay in implementation. The first letter is from the Generic Pharmaceutical Association (GPhA) stating its position that more time is necessary to ensure that a pedigree process can be properly and effectively implemented. This is because many generic companies manufacturer numerous products, which is far more than brand companies, thus, making it a greater burden on the generic manufacturer to implement a pedigree program.

The National Association of Chain Drug Stores (NACDS) and the California Retailers Association (CRA) submitted its second request for a delay based on the direction of the workgroup. They explained that their members would be participating in the newly formed coalition of community pharmacies, manufacturers and distributors to work on the California electronic pedigree implementation plans and milestones. The Health Distributors Management Association (HDMA) and its member wholesalers are organizing this coalition. It is anticipated that the first meeting will be April 25, 2006. They also noted that NACDS members have been actively involved with EPCglobal. NACDS commented that it is working diligently within EPCglobal to research and potentially develop an RFID enabled electronic pedigree system. NACDS stated that it needs more time to ensure that an electronic pedigree can be created that is interoperable among technology vendors and the various states and other stakeholders.

In addition, NACDS and CRA commented that the board should require that all software vendors that offer a solution for the California e-pedigree requirement certify that their software is interoperable. Once there is interoperable software, community pharmacies can begin to pilot and validate the systems to assure that the software can work in real-time so not to affect productivity. They anticipate that the process from the time that interoperable software is available through the phases of testing, validation and deployment across all pharmacies in California, could take as long as two years.

NACDS and CRA offered solutions in the interim such as not to require a pedigree for prescription drugs that are passed through the "normal distribution channel," alerting and educating health care professionals in a timely manner about counterfeit drug products, and enforcing current law against drug importation by non-manufacturers.

Based on concern by the industry that they will be unable to meet the January 1, 2007 implementation date for the pedigree requirement, the Senate Business and Professions Committee has introduced SB 1476 to extend the implementation date to January 1, 2008. This bill also extends the board's sunset provision to January 1, 2010.

The Enforcement Committee members of the E-Pedigree Workgroup acknowledged the amount of work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1, 2007, the committee asked stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. To consider the requests for delay in implementation at the April board meeting, the committee requested that the stakeholders submit with their extension requests implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed concern that they could not meet the 2007 deadline because they are dependent upon the actions of others in the distribution chain.

At the conclusion of the Enforcement Committee meeting, Chairperson Powers and President Goldenberg again requested a progress report from stakeholders to help the board determine when the public can expect to be protected from counterfeiting and diversion of drugs, but noted that the board does not have this report yet.

Joshua Room, Deputy Attorney General, reported on the April 25 group meeting coordinated by the HDMA, titled the California Pedigree Working Group. The goal of the organizers for this group of industry representatives is to have a presentation to the board by the July board meeting.

- **Status on Setting the Standards for Electronic Pedigree – Presentation by Robert Celeste, EPCglobal**

Mr. Celeste attended the board meeting and stated that EPCglobal is an international standards body that develops standards for industries including the health care industry. Mr. Celeste clarified the terms of the standards such as pedigree, serialization, identification of products and carriers.

Mr. Celeste stated that pedigree is the regulatory document that communicates the custody history of a particular medication.

Serialization is a unique number that will be applied to each item within the supply chain and electronic product code is a number in the system that incorporates the numbers and keeps them separate from other numbers with other supply chains so each medication can be uniquely identified.

Mr. Celeste stated that the industry has received a number of requirements from manufacturers and distributors for the system. The process is difficult because all parties within the supply chain

must be identified with security measures for each in place with consideration of globalization. He added that for an example, in Europe there are at least nine different ways to identify pharmaceuticals and in Asia, there are at least four different ways to identify pharmaceuticals. As a global standards body, EPCglobal is trying to develop a unique way of identifying a pharmaceutical product any where in the world. He added that many of the drugs coming into California are produced in other countries and need to be uniquely identifiable in order to protect citizens.

Mr. Celeste stated that EPCglobal is also considering looking at the means to uniquely identify companies within the supply chain and to develop an automated process.

Mr. Celeste stated that they have already identified counterfeit pedigrees and pedigree is not the only solution and this also contributes to the complication of the process. He added that security measures are split between the physical device and the network environment so each would have to be copied to thwart the system.

Mr. Celeste stated that a standardized agreement is needed and the true nirvana of track and trace is being able to find any object within the world at any given time. Every time the product is moved through the supply chain it adds another layer to the pedigree document and this results in redundant data.

Mr. Powers stated that motivation for success in this process is facing the fact that perhaps 25 percent of all drugs in the near future will be counterfeited and this is unacceptable.

Mr. Celeste stated that the pedigree messaging standard is now being developed and will go through ratification and certification will be created around that standard. The work group is developing a working draft with performance requirements. In development of test cases, he described a prototype event where a number of vendors and end users meet with their products to assure they can interoperate with each other and develop standardized usage guidelines.

Mr. Jones asked Mr. Celeste if EPCglobal has considered a marketing effort to target those that must adopt the standard.

Mr. Celeste stated that EPCglobal's marketing efforts includes participating in the standards development effort and the standard is free and can be downloaded.

Joshua Room, Deputy Attorney General, asked for clarification on the reference Mr. Celeste made for an endorsement from the board or other regulatory agencies as to whether EPCglobal's standards meet the criteria for the laws and regulations.

Mr. Celeste stated that EPCglobal does not have this type of endorsement and it would be beneficial that this complies with California's requirements.

Oren Peacock, representing CVS Pharmacies, stated that they have been involved with EPCglobal from the beginning and the only thing missing is a target date.

Mr. Celeste stated that the last call working draft would most likely be available in the next four weeks and the prognosis for a ratified standard is October 2006. The conformance requirements are in development and the next event is a prototype event during the summer and once the standard has been ratified.

Gill Preston, representing Johnson and Johnson, expressed concern that it would be difficult to meet the compliance deadline of January 1, 2007, without a national standard in place. He added that Johnson and Johnson is interfacing with customers and making every reasonable attempt to meet various legislative deadlines but there are many variables.

Mr. Fong asked what steps have been taken within the generic drug industry to advocate a standardization that is supported by ECPglobal or another organization for implementation.

Mr. Preston responded that as members of the Generic Pharmaceutical Association, they attempt to adhere to the same standards.

Sean Brown, representing the Generic Pharmaceutical Association, stated that the association is currently in the process of an industry wide survey of all of their members for a consensus concerning action to take and a target date. He added that it is in everyone's interest to protect the security of the supply chain and patients' welfare.

Fred Mayer, representing Pharmacists Planning Services, Inc., stated that World Health Organization states that the 10 percent of all drugs currently in the world are counterfeit. As a consumer advocate, he asked if the pedigree could determine if drugs manufactured in another country could be authenticated. He expressed concern that this doesn't address the real issue when many are purchasing drugs from the Internet. He added that the high cost of drugs is the issue.

Elizabeth Gallenagh, State Director of Affairs, representing HDMA, stated that they hope to provide the board with a consensus on what needs to be achieved in order to reach implementation.

Steve Gray, representing Kaiser Permanente, commended McKesson for organizing and generously funding the meeting.

The board again requested a progress report on what industry has specifically done to implement California's standards, what remains to be done, and a timeline for implementation. The safety of the state's prescription drugs rest in the swiftest implementation.

The California Pedigree Working Group agreed to have this report to the board by July 1.

REGULATION HEARING

Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions – Proposed Amendment to Repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713

President Goldenberg read the following instructions for the regulation hearing:

This hearing is to consider adopting requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR § 1717(e) and to add 16 CCR 16, §1713, as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

Testimony in Support:

Bob Hansen, PharmD., Vice President Pharmacy Services, Asteres Inc.

Dr. Hansen referred to the written testimony from Asteres, Inc., submitted on January 12, 2006, describing the ongoing contact with the Board of Pharmacy for guidance on the ScriptCenter, a prescription refill delivery kiosk, and the development of the ScriptCenter.

Dr. Hansen stated that California was the first state to approve the use of ScriptCenter or kiosk-type delivery box. Since then, eight states have approved its use and three more states are considering regulations that would allow the use of ScriptCenter. He added that there have been over 37,000 deliveries from the units and with two companies manufacturing the units, the numbers have increased. Asteris Inc. has 7,500 registered patient users.

Dr. Hansen stated that the initial premise of the automated system was to avoid long lines for patients during peak times. He reported that between the hours of 4 and 6 p.m., 33 percent of prescriptions are picked up at the pharmacy. After hours use only accounts for approximately about 5 or 6 percent usually on Saturday or Sunday when the pharmacy is closed between the hours of 5 and 6 p.m.

Dr. Hansen stated that the basic age group using the delivery unit is between 40 and 50 years of age, 7 percent average age 65 or older, and 6 percent are 26 or younger.

Dr. Hansen referred to written comments provided in the board packet which included the board's data reports on medication errors from citation and fines. He noted that the wrong patient getting medication occur 6.2 percent of the time. The ScriptCenter has delivered the correct bag of medications to patients every time.

Richard Mazzoni, representing Albertsons/Sav On

Mr. Mazzoni thanked the board for considering the regulation and he expressed support of the proposed regulation.

Bill Holmes, representing ddn Corporation

Mr. Holmes stated that the technology for the delivery machines is not new and the main focus is patient safety and the opportunity to prevent medication errors at the point of sale. He added that among thousands of deliveries, there hasn't been a single instance of delivery to the wrong patient. He added that we have the technology that can prevent errors. Their patients tell them that they appreciate that the use of the delivery machines allows them to start medication therapies earlier because they can pick up their medications when the pharmacy is closed.

Steve Gray, representing Kaiser Permanente

Dr. Gray acknowledged and thanked the board for the amendments incorporated into the language dated April 19 from the Legislation and Regulation Committee Meeting. He added that Kaiser Permanente supports the changes made.

Testimony in Opposition:

Fred Mayer, R.Ph., M.P.H., representing Pharmacists Planning Service, Inc. (PPSI)

Mr. Mayer also acknowledged the amendments to the proposed regulation to help clarify consumer issues.

Mr. Mayer stated that the PPSI has concerns and referred to the information and 18 exhibits they submitted for the October 25, 2005, Board of Pharmacy packet and he asked that this be reintroduced at this meeting and submitted to the Office of Administrative Law for review.

Mr. Mayer referred to section 201.57 of the Code of Federal Regulations, requiring pharmacists to distribute medication guides with prescriptions to patients. He referred to a study published by Public Citizen that revealed only one out of 20 pharmacies surveyed gave out medicine guides and the remainder did not. He introduced the study as exhibit 19.

Mr. Mayer expressed concern that pharmacists are not counseling patients enough now and that by using these delivery units, consultation will decrease even further. He added that it isn't clear what the definition of "up to the pharmacist's discretion" is and stated the proposed regulation is ambiguous.

Mr. Mayer introduced as exhibit 20, an article published in the September 26, 2005, titled "Duane Reade on fast track with DR Express. The article states that Duane Reade, a regional chain with 250 stores in New York and New Jersey has immediate video conferencing with pharmacy staff on all of their 212 kiosks.

Mr. Mayer also expressed concern about how patients would contact their pharmacist as they use the system. He added that another concern is for non-English speaking patients and he asked how the board would deal with this issue.

Mr. Mayer introduced as exhibit 21 a report titled "Probe Finds Food and Drug Needs More Muscle" that shows that two thirds of the studies conducted have no post market surveillance. He added that this is wrong. He stated that more consultation is needed, not less.

Mr. Mayer referred to SCR 49 and a prescription error study by Senator Jackie Speier and he asked the board to delay any action on the proposed regulation until the results of the study are revealed. He added that it would not improve prescription errors by using kiosks. He asked that the board delay action until the results of this study are revealed.

Mr. Mayer stated that if kiosks are approved, PPSI requests that all kiosks have video conferencing abilities for delivery of all medications, especially those with black box warnings.

Mr. Mayer introduced as exhibit 21, a Medication Guide for Non-Steroidal Anti-Infammatory Drugs (NSAIDs). He added that that 16,000 deaths occur based on a Stanford study. He added that after seven years of petitioning the Food and Drug Administration, black box warnings on non-steroidal drugs and medication guides will be distributed to everyone. He add that these drugs should not be used in kiosks.

Mr. Mayer stated that if kiosks are approved, PPSI requests that all kiosks have similar video conferencing such as the Duane Reade's DR Express available.

Mr. Mayer expressed concern that Constrolled Substance II-III prescriptions should not be available in kiosks. He added that there is an epidemic of overuse of Vicodin. He asked how the pharmacist would counsel patients on Controlled Substances III – V prescriptions.

Mr. Room referred to Mr. Mayer's question regarding the ability to use these machines under current regulations for all controlled substances. He added the regulation as currently constituted, would permit these machines to be used to deliver controlled substances. He added that if the board wishes to exclude these machines from delivering any scheduled drugs, then this would require an additional amendment.

John Cronin, representing the California Pharmacists Association

Mr. Cronin referred to written comments submitted on behalf of the California Pharmacists Association (CPhA).

Mr. Cronin stated that the CPhA believes that these devices are basically safe and represent a useful tool for consumers but the CPhA does not believe that the board's regulation ensures that the use of these machines will further a high standard of patient safety, promote good patient care and advance pharmacist-patient communication.

Mr. Cronin referred to section 1713(d) of the California Code of Regulations where the language states that a pharmacy may use an automated delivery device to deliver previously dispensed prescription medications, provided all the different things listed.

Mr. Cronin stated that "previously dispensed" indicates that the patient has had this drug before. In reading the comments, this was the intent of adding the language. He referred to CCR section 1713(g) where it states "because they have been previously dispensed to the patient by the pharmacy in the same dosage or strength with the same written directions." Mr. Cronin stated that this seems to imply that the prescription was filled at that pharmacy before. He added that the board's intent must to be consistent between the two sections.

Either the patient had the prescription before from another pharmacy, or, there is a requirement that the prescription must be filled in the pharmacy where the devices are located.

Mr. Cronin stated that the language should allow retail pharmacies to compete with mail order pharmacies. He added that mail order pharmacies never fill an original prescription, but prescriptions that have been filled before; because they are unable to perform face-to-face consultation and consequently do not want new prescriptions. He asked if this is the board's intent; that this refers to a previously dispensed medication that would qualify for inclusion in these devices.

Liberty Sanchez, representing the Law Offices of Barry Broad, on behalf of the United Food and Commercial Workers Union (UFCW) in Opposition of the Proposed Regulations.

Ms. Sanchez referred to written comments dated April 10, 2006, submitted to the board by the UFCW.

Ms. Sanchez stated that the UFCW requests the board to conduct a more thorough study of the issue prior to promulgating the regulations. The UFCW believes that as drafted, the regulations have a lot of statements and a lot of ambiguity. The UFCW has concern that the underlying purpose of adopting the regulations is more of a consumer convenience than of consumer protection and safety.

She added that specifically, the UFCW is concerned that the consent form the patient must complete isn't clear enough for patients to make what an informed decision about giving consent.

Ms. Sanchez stated that the regulation provides that "providing a means to speak to a pharmacist or make a call on a 1-800 number" when a patient makes such a request is not sufficient. She added that a "means" could be interpreted to mean, we have the phone, we have the 1-800 number, but no one is actually there to answer the 1-800 number.

Ms. Sanchez stated that the UFCW is concerned that there are different types of kiosks and some might be better than others and this hasn't been thoroughly investigated. The UFCW does not believe that the proposed regulations provide an appropriate method for patients who encounter a broken down machine to understand what to do to secure their medication in an alternative manner.

Ms. Sanchez stated that UFCW is very concerned about the lack of discretion afforded pharmacists in determining whether or not these machines can be placed in their pharmacies and if so, what types of prescriptions can be dispensed from the machines, particularly in light of the fact that the pharmacist would still be liable if errors are made if the machine breaks down, or if the machine erroneously dispenses the wrong drug, etc.

Ms. Sanchez stated the UFCW is requesting that the liability issues be addressed and amended into the regulations. She added that it needs to be clear that pharmacists have complete discretion over what prescription drugs are dispensed through the devices and in order to ensure that discretion; the pharmacist should be protected from any discipline or discharge from his or her employer when the pharmacist is exercising his good faith professional judgment. She stated that the UFCW is suggesting that the pharmacist be expressly immune from licensure sanctions if an automated delivery device malfunctions or an error results from the patient's use of the machine.

Ms. Sanchez stated that the UFCW is opposed to the proposed regulations and urges the board to study the issue further before adopting the regulations.

Mr. Powers asked Ms. Sanchez if there were other issues regarding vagueness that were not mentioned in Mr. Gusman's letter.

Ms. Sanchez responded that the only vagueness issues addressed were the lack of clarity in the written consent form and what it should look like and the type of communication needed between the pharmacy and the patient to convey how the machine works, what the patient needs to do and what recourse the patient has if the machine malfunctions, etc. She added that the issues she raised were the 1-800 number, the phrase in the proposed regulations "provide a means to immediately reach the pharmacist or a pharmacist via the 1-800 number." She added that "provide a means" is insufficient and should be clarified so patients have the ability for actual immediate contact, not just a means for immediate contact. Additionally, the UFCW is very concerned about the liability concerns and the lack of clarity there.

Ms. Sanchez stated that another issue Mr. Gusman raised in his letter was a discretion issue in relation to the pharmacy and the pharmacist regarding the ability to determine if kiosks should be placed in the pharmacy and what exactly can be dispensed in them.

President Goldenberg closed the public comment period, as there were no further comments.

Mr. Room referred to Mr. Cronin's comment about the use of the phrase "previously dispensed." Mr. Room stated that the language is from section 1707.2 of the California Code of Regulations and the intent was to use these machines synonymously in situations that consultation is not automatically required.

Mr. Room stated that if the board wants to respond to one of the clarification requests by the UFCW, it could change section (d) (5) to make it more of an affirmative duty to provide consultation by removing: "a means for each patient to request and obtain." The change could be adopted by the board as part of its vote and would require a 15-day notice period for further comment.

Ms. Harris stated that the board was provided with a copy of the April 19 version of the language with modifications received from the Legislation and Regulation Committee and

comments submitted in writing from the public. She added that the strikeout represents deletion of the language and the double underline represents language that was added.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy adopt the proposed amendment to repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713 with an amendment to the April 19 version of the language in section 1713 (d)(5) as follows:

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated delivery device to deliver previously dispensed ~~refilled~~ prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication ~~mediation~~ to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed ~~refill~~ prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient. ~~The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.~~

(6) The device is located adjacent to the secure pharmacy area~~licensed pharmacy counter~~.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy. However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

SUPPORT: 8 OPPOSE: 1

Mr. Mayer requested that the board have the Office of Administrative Law consider the conflict of interest issue for pharmacist member of the board to be voting on this regulation.

MOTION: That the Board of Pharmacy delegate authority to the executive officer to respond to further comments regarding the proposed amendment to repeal 16 CCR section 1717(e) and to add 16 CCR section 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions unless new negative comments are received.

M/S/C: FONG/CONROY

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

Pending Regulations

Board Approved – Pending Administrative Approval

- **Adoption of Proposed Addition of 16 CCR Section 1727.1 – Exemption for Intern Addresses from Posting On-Line**

  Chairperson Jones stated that on October 25, 2005, the board approved CCR 1727.1 to exclude the posting of pharmacist intern addresses on the Internet. This proposed regulation is undergoing administration review. It is anticipated tht this regulation will be effective in late 2006.

Board Approved - Awaiting Notice

- **Proposed Amendment of 16 CCR Section 1706.2 – Abandonment of Application Files for Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringes Distributor and Designated Representative**

  Chairperson Jones stated that this regulation would add veterinary food animal drug retailer, needle and syringe distributor and designated representative to the abandonment of files provisions of this section.

- **Proposed Amendment to 16 CCR Section 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge" (Section 100 Technical Change)**

  Chairperson Jones stated that the term "Designated Representative-in-Charge" was added to Pharmacy Law in 2005 by Senate Bill 1307 (Chapter 857, Statutes of 2004) and became effective on January 1, 2005. The board voted to amend this regulation during the February Board Meeting to conform with the law.

- **Proposed Amendment to Repeal 16 CCR Section 1717.2 – Notice of Electronic Prescription Files**

  Chairperson Jones stated that the purpose for repealing the regulation is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the initial Statement of Reasons and Notice documents.

- **Proposed Amendment of 16 CCR Section 1760 – Disciplinary Guidelines**

  Chairperson Jones stated that this rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. The Guidelines will be ready for public notice and the formal start of the rulemaking process at the October board meeting.

- **Proposed Amendment to 16 CCR Section 1775.4 – Reschedule of an Office Conference to Contest a Citation**

  Chairperson Jones stated that in 2003, the board revised its system for issuing citations to make its procedures more consistent with the procedures used by other boards with the Department of Consumer Affairs. During the revision process, a provision in CCR 1775(a) that allows a person or entity to only reschedule an informal office conference one time was inadvertently left out of the revised regulations. The board voted to restore this provision during the February Board Meeting.

- **Proposed Amendment to 16 CCR Section 1780 – Update the USP Standards Reference Material (Section 100 Technical Change)**

  Chairperson Jones stated that the board voted to revise section 1780 to update the USP standards to require the 2005 USP revision at the February 2006, board meeting.

- **Proposed Amendment to 16 CCR Section 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"**

  Chairperson Jones stated that during the February 2006 board meeting, the board voted to revise section 1780.1 and 1781 of the California Code of Regulations to replace the term "exemptee" with "designated representative" to conform to the passage of SB 1307 (Chapter 857, Statutes of 2004) which took effect January 1, 2006.

- **Proposed Adoption to 16 CCR Section 1784 – Self-Assessment of a Wholesaler by the Designated Representative-In-Charge**

  Chairperson Jones stated that staff completed its internal review of the assessment form. It will be publicly noticed and brought to the board for action at a future meeting.

- **Proposed Repeal of 16 CCR Section 1786 – Exemptions for a Supplier (Section 100 Technical Change)**

  Chairperson Jones stated that this regulation requires a wholesaler to immediately return a certificate of exemption of a designated representative leaves the employment of the wholesaler. This regulation is based on past pharmacy law that required certificate of exemption to be linked to

a specific licensed wholesaler location, not to the designated representative as current law requires. Consequently, CCR Section 1786 is no longer a meaningful regulation and should be repealed.

Awaiting Board Review and Action

- **Addition to the California Building Code – 24 CCR Sections 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies.**

The California Building Standards Commission (CBSC) has asked the board to review and update pharmacy building standards in the building code, in preparation of the CBSC adoption of the 2006 International Building Code and 2006 International Fire Code, the 2005 National Electrical Code, and 2006 Uniform Mechanical Code and Uniform Plumbing Code, in CCR, Title 24. The CBSC anticipates adopting the new standards in early 2008.

Staff reviewed and updated the relevant building code sections. The board needs to review the proposed changes, and if acceptable, vote to allow the CBSC to move forward with the code revisions.

John Cronin, representing the California Pharmacists Association, referred to the reference in this regulation that refers to compounding areas and states that the pharmacy shall have a designated area for preparation of sterile products for dispensing. He added that this did not seem to limit the requirement to pharmacies that dispense sterile compounded products. It seems to imply that it applies to all pharmacies. He asked for clarification. He referred to sections 390A.3 and 505.12.2.

490A.3 Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.
2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solution.

There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.
5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:
   (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
   (b) An ISO class 5 cleanroom.
   (c) A barrier isolator that provides an ISO class 5 environment for compounding.

Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

Notation
Authority: B & PC § ~~4008~~ 4005
Reference(s): B & PC §§ 4008 and 4081 4005, 4127.7. and 4201

505.12 Pharmacies – Compounding Area for Parenteral Solutions. (For CA – Board of Pharmacy) Any pharmacy that prepares sterile injectable products shall have a designated area for the preparation and dispensing shall:

1. Be ventilated in a manner not interfering with laminar air low.
   NOTE: For additional pharmacy building atandard requirements, see Chapter 4A, Section 490A, California Building Code.

505.12.1 Pharmacies – laminar flow biological safety cabinet. (For CA – Board of Pharmacy) In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.

5-5/12/.2 Pharmacies Compounding Parenterial Solutions from One or More Nonsterile Ingredients. Any Pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

(d) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
(e) An ISO class 5 cleanroom.
(f) A barrier isolator that provides an ISO class 5 environment for compounding.

MOTION: That the Board of Pharmacy amend the language in the California Building Code, Title 24, California Code of Regulations, sections 490A.3 and 505.12 related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies as follows:

M/S/C: FONG/SCHELL

SUPPORT: 9 OPPOSE: 0

REGULATION HEARING

Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Pharmacy – Proposed Amendment to 16 CCR Sections 1793.7 and 1793.8.

President Goldenberg read the following instructions for the regulation hearing:
This hearing is to consider adopting requirements to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes; proposed amendment to 16 CCR section 1793.7 and to add 16 CCR section 1793.8, as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally

adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

Testimony in Support

Peter Ambrose, University of San Francisco, School of Pharmacy

Dr. Ambrose stated that he is the primary investigator of the study to evaluate the accuracy of technicians and pharmacists in checking unit dose medication cassettes that was presented to the board earlier during this meeting. He offered the board his assistance in answering questions on the study during the regulation hearing and added that he is impressed with the nature of the data that demonstrates that pharmacists have a positive impact on improving medication safety.

Rita Shane, Director of Pharmacy Services, Cedars-Sinai Medical Center

Dr. Shane stated that during the last 13 years while in discussions with the Board of Pharmacy regarding this issue, she was struck by the evolution of professional awareness of the pharmacist's role in the area of patient safety. She added that the focus has been whether this is safe for patients in California and that every decision to change regulatory language weighs risk versus benefit.

Dr. Shane stated that during her participation with the board as part of the study, she observed the literature and the abundant data demonstrating the value of pharmacists. She added that she supports the regulation; not just for the patients that come to Cedars-Sinai Medical Center, but any acute care practice setting. Her concern is that without the regulation, they now have data demonstrating real harm to patients in California.

Dr. Shane stated that she is encouraged by ongoing initiatives to provide safety to every patient, regardless of where they access the health care system. She added that this study is one example and she hopes that the evidence and all of the information presented over the last 13 years is compelling enough. She stated that she continues to see the practice of pharmacy move forward in the state, focusing on patients.

Kelli Haase, Pharm.D., FCSHP

Dr. Haase referred to written testimony that was provided in the board packet. She stated that she is a clinical pharmacist at St Joseph's Medical Center in Stockton California. She added that she was asked to come and say a few words from a clinical pharmacist point of view of the type of activities that the pharmacist could be involved in if they weren't involved in checking cassette drawers that were filled by certified pharmacy technicians.

Dr. Haase stated that during the course of her day is in a decentralized service, or a service that the pharmacist offers outside the pharmacy, is to interact with the other medical professionals in the hospital and also with the patient. The time spent outside the pharmacy, allows her to look for drug-drug interactions and spend significant amounts of time with the patients and providing patient counseling.

Dr. Haase thanked the board for the opportunity to testify before the board.

Ann Rosenblack, Nursing Manager, Cedars-Sinai Medical Center

Ms. Rosenblack stated that the purpose of her testimony is to offer a clinical perspective of the amended changes from the nurses' point of view. Ms. Rosenblack added that this is her 35th year in the nursing profession and she has worked for the last eight years at Cedars-Siani Medical Center. She stated that the physical presence of the pharmacist on the floor assisting patients and nurses at the hospital is invaluable.

Ms. Rosenblack referred to the Institute of Medicine Report regarding the deaths that occur yearly at the hands of caregivers and the movement during the last few years for public awareness of safety.

Dr. Fong referred to Cedars-Sinai's training and commitment and asked how other hospitals can replicate this effort with the same assurances and achieve the same objective.

Ms. Rosenblack stated that the main focus of the study is safety because of the results from Institute of Medicine Study. She added that the study did not take a lot of money or extra people but it did focus on teaching pharmacy technicians and this can be replicated in any area.

John Cronin, representing the California Pharmacists Association

Mr. Cronin stated that the California Pharmacists Association supports this regulation and the proposed regulation is consistent with what the board should be doing and consistent with CPhA's policy as well.

Mr. Cronin stated that the board received approximately 38 comments in favor of the proposed regulation, primarily from pharmacists and this attests to the importance of the regulation.

Robert Mower, Pharmacist, UC David Medical Center, on behalf of the California Society of Health-System Pharmacists

Mr. Mower referred to the written testimony he provided to the board and he demonstrated a medication cassette and explained the process when a fill list is generated by a physician's order. The pharmacist then puts the information into the pharmacy information system and then prints a fill list. The fill list is taken by the pharmacy technician to pull the drugs and place them in a drawer. The pharmacist then checks the order to make sure it is accurate. He added that a technician can very easily verify that orders placed in the drawers are accurate. He added that he supports the proposed regulation and that it will help move the pharmacy practice forward and allow a pharmacist to be on the floor with the nurse and the physician, to assure that the correct medications are prescribed.

Darren Besoyan, Pharmacy Technician III UC Davis Medical Center, Representing the California Society of Health-System Pharmacists

Mr. Besoyan presented the following testimony:

> Good afternoon, My name is Darren Besoyan and I am currently a Supervising Pharmacy Technician at UC Davis Medical Center. I started my career over 19 years ago in the acute inpatient setting working closely with pharmacists in an Operating room satellite pharmacy. I also serve as a Student Pharmacy Technician Internship Coordinator.
>
> Technicians provide a vital role in facilitating quality patient care through their trained field of expertise. Technicians can, and should be used to a greater extent. When technicians perform technical medication filling and checking activities, pharmacists can then pursue duties in their field of expertise, medication management at the patient's bedside. Both the pharmacist and the technician along with physicians and

nurses are needed to ensure appropriate, safe and timely medications are provided to patients in the hospital. We, as technicians, are capable of so much concerning patient medication safety, especially when it comes to performing the repetitive, non-discretionary functions related to the practice of pharmacy. This proposed "tech-check-tech" regulation, will provide the infrastructure necessary to improve patient medication safety in an inpatient setting, by allowing properly trained technicians to function at their maximum and allowing pharmacists to utilize their medication expertise to provide direct medication management to patients. Thank you for taking the time to address this important consumer safety issue.

Jerry Gonzalez, Pharmacist registered in California for 25 years, representing CSHP and North Bay Health Care System

Dr. Gonzalez expressed concern about how we would replicate and assure that process control around the training and accountability for accuracy of pharmacy technicians. Mr. Gonzalez stated that at the last three hospitals where he practiced as director of pharmacy, that have implemented similar processes controls such as those practiced by Cedars-Sinai and Long Beach Memorial Hospital, to improve their performance of cart filling check by pharmacists. He added that he is confident that the CSHP can take the lead to provide a mechanism for education and program roll-out.

Opposing Testimony

Liberty Sanchez, from the Law Offices of Barry Broad, representing the United Food and Commercial Workers Union (UFCW)

Ms. Sanchez stated that the UFCW shares the concept that there is a problem, but they disagree with what the solution is. She added that the UFCW oppose the proposed regulations.

Ms. Sanchez stated that it is important for pharmacists to be available in all capacities, and in particular, in acute care facilities. She added that the appropriate solution to the problem is hiring more pharmacists, not doling out tasks that are appropriately within the statutory and regulatory confines of the pharmacist's profession to technicians.

Ms. Sanchez stated that the board's obligation is to ensure that patient and consumer protection is upheld. Any regulations that are adopted must not supersede or be contradictory to existing statutory law. She added that the proposed regulations are clearly contradictory to existing statutory and regulatory law.

Ms. Sanchez referred to the UFCW's written comments submitted on April 17 and the board minutes from the January 2001, October 2001 and October 24 and 25, 2002 meetings that include an opinion from former Deputy Attorney General William Marcus, that the board did not have the authority to promulgate regulations. Further, page 5 of the October 2002 board

minutes, states: "the board decided that the proposed changes would require legislation." She added that legislation proposed by Senator Aanasted in 2003 and 2005 (SB 393 and SB 592) failed passage in the Legislature. She added that now, four years after the board determined that it did not have the authority to promulgate regulations, that it before the board again. She stated the UFCW respectfully contends that the board does not have the authority to promulgate these specific regulations.

She stated that contrary to proponents' contention that the proposed regulation will promote patient safety in the acute care setting based on the idea that there will be additional training provided to pharmacy technicians who check the work of other pharmacy technicians. Due to a lack of specificity in the proposed regulations about what the advanced training and education is, particularly when you compare that to the truly advanced training and education that pharmacists have, there is no assurety that patient safety will be promoted by allowing pharmacy technicians to undertake this task. She expressed concern that if the proposed regulations pass, there would be additional requests in the future to expand the duties of technicians.

Ms. Sanchez stated that the underlying published study is not sufficient to make such a sweeping change in California. She added that the underlying published study in 1998 observed only 39 pharmacy technicians, 29 pharmacists and approximately 190,000 doses of medication. There was only a distinction of 0.3 accuracy rate of the pharmacist and the pharmacy technicians were above 99 percent. Ms. Sanchez added that the only rationale for the regulation is to reduce costs by reducing the need to have multiple pharmacists in the acute care setting.

Ms. Sanchez stated that liability issues are also a concern for both the pharmacist and the nurse who administers medication to a patient since nurses will be the final person to handle the medication. She added that they are strongly opposed to adoption of these proposed regulations.

Martha Mason, Pharmacist, San Quentin State Prison

Ms. Mason stated that the prison has 5000-6000 patients. She expressed concern about technicians checking other technicians because technicians have made errors. She added patients in the prison system are a captive audience and sometimes may not be aware that they were administered the wrong prescription. She expressed concern that there would be more complaints about lack of care if the regulation is approved and she added that mistakes are very common.

There being no further comments, President Goldenberg closed the regulation hearing.

The board discussed the regulation.

MOTION: The Board of Pharmacy adopt the proposed amendments to Title 16, California Code of Regulations, Sections 1793.7 and 1793.8 as follows:

Amend Section 1793.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Adopt Section 1793.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist. Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code.
Reference cited: Sections 4007, 4038, 4115 and 4202, Business and Professions Code.

M/S/C: SCHELL/HIURA

SUPPORT: 7 OPPOSE: 2

Legislation Report and Action

Board Sponsored Legislation

- **AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs.**

  Chairperson Jones stated that this bill is sponsored by the board to establish standards for pharmacies that compound drugs. The board approved this legislative proposal at its January 2005 meeting and the bill is now on the Senate Floor.

- **AB 2408 (Negrete McLeod) Pharmacists, Pharmacies, and Nonresident Pharmacies.**

  Chairperson Jones stated that this bill is sponsored by the board and would update the definition of a pharmacy, nonresident pharmacy, and the professional practice of pharmacy. The board approved draft legislation at its February 2006 meeting. This bill is currently before the Assembly Appropriations Committee.

  Steve Gray, representing Kaiser Permanente, had a number of questions regarding this bill at the committee meeting. One item the committee directed for board discussion at this meeting is whether the policy outlined in AB 2408 conforms to board recommendations adopted at the January Board Meeting regarding the Licensing Committee's recommendations for regulating pharmacists who provide services to Californians from outside California.

  In section 4051(c), if a pharmacist outside California provides cognitive services to Californians in this state, the pharmacist either needs to be licensed as a pharmacist in California, or work/be associated with a nonresident pharmacy that is licensed in California.

  Mr. Room stated that this language is consistent with how other professions regulate licensees and how the dispensing function is handled under current law.

  Dr. Gray expressed concern that it would be illegal if a specialty pharmacist called a consulting pharmacist in another state for an opinion.

  Mr. Room stated that only direct-to-patient services would require a license.

Mr. Gray also expressed concern that the statute would allow medical records to be reviewed by any authorized officer of the law without a search warrant, a subpoena or the patient's permission. He suggested a revision to the language to make a distinction between records related to drug dispensing and records that are kept by a pharmacist that are related to the management of drug therapy.

Mr. Room stated that he felt the distinction is already in statute in that the law makes dispensing and acquisition to disposition records accessible and only open for inspection by the board.

The board determined that technical changes to the bill would be addressed and directed staff to proceed.

- **SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill.**

Chairperson Jones stated that the board approved eight proposals for the omnibus legislation, however only three of the eight proposals are currently in the bill. A hearing on this bill was held in the Senate Business and Professions and Economic Development Committee on April 24. Board staff will work to ensure the inclusion of these remaining provisions by the Senate Business and Professions Committee.

Approved Proposals in SB 1475

B&P 4104 Licensed Employee, Theft, Impairment: Pharmacy Procedures.
B&P 4162 Wholesalers Surety Bond Requirements.
B&P 4180-4182 and 4190-4192 Nonprofit or Free Clinics.

Approved Proposals NOT in SB 1475

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment.
B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device.
B&P 4160 Wholesaler License.
B&P 4127.1 Injectable Sterile Drug Products.
B&P 4073 Substitution of Generic Drug, Check off Box on Electronic Prescriptions.

Chairperson Jones that the board received a request from MedImmune, Inc. to amend Business and Professions Code section 4162.5(a)(4) related to surety bond requirements. On March 21, 2006 the board received a letter from Colleen Chawla, Government Affairs Manager for MedImmune, Inc.. MedImmune Inc., requesting that the board sponsor legislation for an amendment. Chairperson Jones stated that this is a technical change.

Mr. Room stated that anyone with a new drug application is exempted from wholesaler licensure requirements for that particular drug as long as it is the only drug they are selling.

For biologics there is a separate process for drug approval with the FDA although it is similar to a new drug application.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy approve the request from MedImmune, Inc. to amend Business and Professions Code section 4162.5(a)(4) related to surety bond requirements as follows:

4162.5 (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application <u>or a biologics license application</u> has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application <u>or a biologics license application,</u> and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011,

unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SUPPORT: 9 OPPOSE: 0

- **SB 1476 (Figueroa) Board Sunset Extension Bill.**

Chairperson Jones stated that this bill would extend the board's sunset date two years, from 2008 to 2010. The board's sunset report to the Legislature would be similarly delayed until September 2008. Additionally, the measure would move the implementation date of the electronic pedigree requirement from January 1, 2007 to January 1, 2008. He added that SB 1476 was heard on April 24 in the Senate Business and Economic Development Committee.

The board expressed concern about supporting a delay in implementation of the pedigree requirement. However, after discussion, the board agreed to support this provision.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy write a letter of support of SB 1476 (Figueroa), expressing appreciation to the author for her long standing consumer protection efforts and conveying the board's reservation in delaying the implementation date of the electronic pedigree because of its public health impact while recognizing that the industry is moving forward.

SUPPORT: 9 OPPOSE 0

2006 Bills of Interest

- **AB 2308 (Plesca) Ambulatory Surgical Centers**

Chairperson Jones stated that this bill requires the Department of Health Services (DHS) to convene a workgroup to develop licensure criteria to protect patients receiving care in ambulatory surgical centers, and to submit workgroup conclusions and recommendations to the appropriate policy committees of the Legislature no later than March 1, 2007, and revises existing law to replace the term "licensed surgical clinic" with "ambulatory surgical centers."

Ms. Harris stated that a licensed surgical center or clinic must be licensed as a clinic with the Board of Pharmacy to co-mingle drugs. This bill expands the surgical clinic to a surgical center and includes licensed Medicare certified facilities and expands the number of facilities that require licensure with the Board of Pharmacy.

A comment made from the bill sponsors at the California Ambulatory Surgery Association was that the bill attempts to change the definition of a surgical clinic under California Code of Regulations section 1204, to ambulatory surgical centers to make it consistent with federal

law and makes various conforming changes to the language. An ambulatory surgery center would have to be licensed to purchase drugs at wholesale for physicians to distribute.

- **AB 2583 (Nation) – Dispensing Prescription Drugs and Devices: Refusal to Dispense**

Chairperson Jones stated that AB 2583 requires the Board of Pharmacy to create and provide all licentiates a notice that must be posted by licentiates that inform patients of their right to timely access to prescribed drugs and devices even if licentiate refuses to dispense the drug or device based on ethical, moral, or religious grounds. The board is not the regulator of all these licentiates. Moreover, if licentiates comply with legal requirements for these with moral, ethical or religious grounds there must be procedures to ensure patients get their drugs on time regardless.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose AB 2583 (Nation), unless amended.

SUPPORT: 9 OPPOSE: 0

- **AB 2743 (Matthews) Pharmacists: Ancillary Personnel.**

Chairperson Jones stated that AB 2743 would limit the number of ancillary personnel in a pharmacy to eight and defines ancillary personnel as pharmacy technicians, pharmacy technician trainees, interns, clerks and typists. The intent is to increase the amount of pharmacy technicians in a pharmacy. A hearing was scheduled on April 25 in the Assembly Business and Professions Committee.

John Cronin, representing the California Pharmacists Association, stated that CPhA is trying to establish a task force with the CSHP, the UFCW and the CRA, to address the entire issue of ancillary personnel. This bill will not be moved.

- **AB 2986 (Mullin) Controlled Substances: Prescription Requirements.**

Chairperson Jones stated that AB 2986 would require that Schedule IV drugs be added to CURES, along with additional data fields for everything Schedule II-IV drugs dispensed in California.

Steve Gray, representing Kaiser Permanente, stated that this bill is intended for California to receive available federal funds to enhance the CURES system. He added that it adds a tremendous financial burden on all pharmacies and prescribers and will increase the costs of the CURES system. The Department of Justice is the sponsor of this bill.

- **SB 1366 (Aanestad) Controlled substances.**

Chairperson Jones stated that this bill proposes to eliminate security printers and security forms for prescribing controlled drugs and would rely on the CURES program for monitoring the prescriber and dispensing of controlled drugs.

- **AJR 40 (Chan) Medicare Prescription Drugs.**

  Chairperson Jones stated that the California Legislature would memorialize the Congress and President of the United States to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005" to amend the Medicare Part D Drug Program requirements for the nation's disabled and seniors. A letter will be sent to the author's office.

Other 2006 Bills the Committee will Watch

AB 1908 (Karnette) Medi-Cal: Pharmacy Reimbursement.

AB 2057 (Cogdill) Controlled Substances.

AB 2373 (Plescia) Automated Drug Delivery Systems.

AB 2730 (Nation) Medi-Cal: Contract Drug List: Advertising.

AB 2856 (Hancock) Informed Consent: Prescription Medication Off-Label Use.

AB 2877 (Frommer) Prescription Drugs: Importation: Procurement.

AB 2911 (Nunez) California Discount Prescription Drug Program.

ELECTION OF OFFICERS

Treasurer

MOTION: Elect Ruth Conroy as treasurer of the Board of Pharmacy.

M/S/C: JONES/SCHELL

SUPPORT 9 OPPOSE: 0

Vice President

MOTION: Elect Ken Schell as vice president of the Board of Pharmacy.

M/S/C: POWERS/CONROY

SUPPORT: 9 OPPOSE: 0

President

MOTION: Elect Bill Powers as President of the Board of Pharmacy.

M/S/C: ZINDER/JONES

SUPPORT: 8 OPPOSE: 0

Mr. Powers stated that Stan Goldenberg has served as president of the Board of Pharmacy for two years and during this time he has served extraordinarily well for the public and the board; providing initiative and leadership in a variety of areas that are remarkable. Mr. Powers added that President Goldenberg will be a difficult role model to follow and he acknowledged President Goldenberg's many accomplishments.

Mr. Jones also commended President Goldenberg for his commitment as board president and noted that he gave 100 percent.

President Goldenberg stated that it is a true honor to serve on the Board of Pharmacy and he commended staff and board members for setting a level of professionalism, possessing a commitment to serving the public as well as showing a passion for the profession of pharmacy.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

John Cronin, representing the California Pharmacists Association, asked how lack of a quorum would affect committee meetings.

Ms. Harris stated that the board would continue with the committee meetings, however, some committees may have fewer members.

She added that President Powers would announce his appointments to the new committee assignments at the July Board Meeting.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases.

ADJOURMENT

There being no further business, President Goldenberg adjourned the board meeting at 5:15 p.m.

Thursday, April 27, 2006

STRATEGIC PLANNING 2006-2011

Lindle Hatton, PhD, lead the board in the strategic planning process that began at 8:00 a.m. This session ended at noon.

PETITIONS

- **Petition for Reinstatements**
  Kirk Bolas
  Dr. Tracey Moore

- **Early Termination and Reduction of Penalty**
  Morris Stavnezer

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases and petitions for reinstatement, early termination of probation and reduction of penalty.